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Introduction

Funding was provided for a conference on Image-Guided Procedures and Surgical Simulation at the 2001 SPIE Medical Imaging meeting. Funds were used to provide travel reimbursement for speakers, for the cost of putting on a hands-on workshop and for creating a deliverable: a snapshot of the state of the art in image-guided procedures in 2001.

Body:

The organizers of the 2001 SPIE Medical Imaging meeting decided to "retask" the Image Display Conference to have a separate Image-Guided Procedures and Surgical Simulation tract. Funds from the USMRMC and from the Whitaker foundation allowed us to bring in some of the top researchers in this field as well as up and coming young scholars. A short course on surgical simulation and a hands-on workshop were developed.

We had hoped to get at least 20 abstracts so we could fill one day of the meeting, we received more than 90! Since image-guided procedure systems are kinetic, they are often undersold by slide displays so it was decided that we would put on a workshop where systems could be brought in for a hands-on demonstration. Again, our expectations were modest, we were up against two other high-profile workshops and we hoped for 30 to 60 attendees, we got more than 300! So clearly this is an area of some major interest.

KEY RESEARCH ACCOMPLISHMENTS:

The Image-Guided Procedures and Surgical Simulation tract of the SPIE meeting proved to be a great success. Over 60 papers and posters were presented and the workshop generated significant interest in the field.

REPORTABLE OUTCOMES:

In the appendix is a document of providing a snapshot report of the state of the art in Image-Guided Procedures and Surgical Simulations as of 2001.

CONCLUSIONS:

The Image-Guided Procedures and Surgical Simulation Tract for the meeting was a huge success. The hand-on workshop generated significant interest beyond that of the papers.

REFERENCES: NA

APPENDICES: Copies of the Snapshot Document are enclosed.

Image-Guided Procedures 2001 A Snapshot View

July 31, 2001

Robert L. Galloway Jr PhD
Kevin Cleary PhD
Terrance Peters, PhD

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Acknowledgements

A number of these papers arose from the Image-Guided Procedures Track of the 2001 SPIE Medical Imaging Meeting. That meeting was sponsored in part by the Whitaker Foundation and TATRC of the U.S. Army Medical Research and Materiel Command.

The Background paper is a version of a paper written by Dr. Robert Galloway for Annual Review of Biomedical Engineering.

The images on the front cover are provided by

Dr. Robert Galloway, Vanderbilt University
Dr. Kevin Cleary, Georgetown University Medical Center
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Introduction

While medical images have been used to assist surgery for almost as long as there have been medical images, it is only with the rise of image-assisted stereotaxy in the late 1940s that the images were used quantitatively. With the development of computed tomography in the 1970s, medical images as numerical data sets emerged. In the mid 1980's a number of researchers world wide realized that these image sets had value beyond their diagnostic capabilities and with the development of small inexpensive computers set about developing system to exploit the localization and guidance potential in such sets. So here in 2001 we are dealing with a technology which can be considered 15 years old at the most. The field has gone through several steps: First, researchers developed systems which determined and demonstrated what *could* be done. Then work moved forward on the development of metrics for assessing what *had* been done. As we begin to build up a body of knowledge about the guidance of therapeutic procedures we can begin to ask the question: what *should* be done? Image-guidance has proven to be enabling, that is allowing surgeons, interventional radiologists and radiation therapists the confidence to guide treatment to previously "untreatable" locations. It has also proven to be safe, actually reducing OR time and the associated morbidity relative to other approaches to the same therapy. What is only now being assembled is the data on the efficacy of what we now call Image-Guided Procedures (IGP).

While we begin to get data on the long-term outcome of some of the clinical studies, system development, refinement and new procedures continue to emerge. The vast majority of work in the field has been in neurosurgical applications as an outgrowth of stereotaxy, but as analyzed as a health-care issue, neurosurgery is a thankfully small problem. We are beginning to see applications outside of brain surgery and the required, accompanying development of technology associated with those applications. Beyond that we are seeing true integration of multi-disciplinary teams composed of surgeons, radiation therapists, engineers, physicists and computer scientists. Engineering graduate students working with surgical residents, graduate students being funded by clinical departments and residents doing research in engineering laboratories all bode for explosive future growth in the field.

It is that growth and the newness of the ideas, methods and principles of IGP which make this merely snapshot of the field. We are in the first generation of systems and as so often been the case, arrival at generation one merely points up the places where approximation and ignorance of the reality occurs. For the most part, IGP systems treat tissue as if it is rigid and monolithic in construction and function. Those are laughable approximations of reality, but were necessary to make to get IGP systems up and running. Now that we have high-accuracy localization, more sophisticated assessment of registration quality and improved segmentation algorithms we can make the measurements necessary to allow for tissue motion and deformation, for dealing with multi-compartment structures and for using functional information as well as anatomic to guide the delivery of therapy. Beyond that, we are beginning to think about the role of IGP in improving the specificity of therapy delivery, not only treating the disease but actively avoiding damage to healthy tissue. We are also seeing surgeons, interventional radiologist and radiation oncologists being trained from the start with a knowledge of the existence and principles of IGT. They are proving to think about treatment planning and delivery in ways which much different from their predecessors.

In 2000 Kevin Cleary and I were tasked with job of creating an Image-Guided Procedures meeting within the confines of the SPIE 2001 Medical Imaging meeting (San Diego, CA, Feb 17-22). While

the SPIE meeting had had IGP papers in the past, this was the first attempt to focus a section of the meeting on that particular topic. We had hoped to get at least 20 abstracts so we could fill one day of the meeting, we received more than 90! Since image-guided procedure systems are kinetic, they are often undersold by slide displays so it was decided that we would put on a workshop where systems could be brought in for a hands-on demonstration. Again, our expectations were modest, we were up against two other high-profile workshops and we hoped for 30 to 60 attendees, we got more than 300!

So clearly this is an area of some major interest.

The papers composing this manuscript begin with a modified version of a review article that I wrote to lay the foundation for IGP. Following that Dr. Terrance Peters has provided his keynote address on the state of the art in IGP. The next article is a review of Surgical Simulation, an area of explosive growth that uses a number of the principles of IGP but adds layers of tissue modelling and haptic interfaces. Finally, Dr. Kevin Cleary contributes a paper on surgical robotics.

As I said earlier, the field of Image-Guided Procedures is in its infancy. This document is to serve as a snapshot of the field in 2001.

Robert L. Galloway Jr.
July 2001

Background on the development of image-guided procedures

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MOTIVATION FOR IMAGE GUIDANCE

One of the most fundamental forces in the development of surgery and other forms of directed therapy is the need to increase the information available to physicians and to place that information in both spatial and temporal contexts. From such perspectives, the development of surgery, radiation therapy, and now even chemotherapy can be followed. In each field there is a movement to finer and finer preoperative determinations of pathology locations coupled with intraprocedural determinations of therapeutic positions. This process can be seen as progression from providing therapy to a general patient to treating a specific one.

In all therapies, what is needed for successful outcomes is knowledge of the spatial location and extent of a problem. To use surgery as an example, with the advancement of surgical techniques came the need for a surgeon to exactly define the location of his or her instruments. Simple visual inspection gave way to magnifying loupes, loupes to operating microscopes and endoscopes. This relationship between knowing the spatial location and extent of a problem and performing the surgery is so intuitive that only 8 days after the announcement of Roentgen's discovery of X rays, the first image-guided surgery was performed. On January 13, 1896, a woman in Birmingham (UK) buried a needle in her hand. A radiograph was made of her hand, which she took to casualty surgeon JH Clayton to help him in his surgical removal of the needle (1). Here the trauma was known, the shape and size of the surgical target exactly defined. The radiograph reduced the uncertainty of the location of the needle relative to other anatomic structures in that patient. However, because simple radiographs compress three-dimensional spatial relations into two-dimensional images, there remained a degree of positional uncertainty relative to the thickness of the patient's hand. In addition, a radiograph shows only the bony anatomy

clearly; therefore, the surgeon's knowledge of the location of other structures, such as tendons and vessels, was still dependent on his or her understanding of general anatomy.

This same progression can be seen in other therapies as well. Simple external beam, quadrant-directed radiotherapy has been enhanced by stereotactic radiosurgery and therapy; brachytherapy delivers radiation from the inside of the tissue outward; and direct-injection, controlled-release chemotherapy is replacing systemic chemotherapy in certain applications.

As imaging has progressed from simple, static X rays to include tomograms and dynamic imaging, the application of those images to therapy has moved with it. As image sets became three dimensional in space and time, the technological complexity of putting them to use increased dramatically. This necessitated the creation of physician-engineer teams to develop devices and techniques, a collaboration that has grown to become the field of image-guided procedures (IGPs).

Because preinterventional images exist for the vast majority of therapeutic procedures, what constitutes an IGP? One definition is that in an IGP, images are used quantitatively. That is, their spatial parameters carry equal or greater weight than their gray-scale parameters. Thus, the mere presence of tomographic images in an operating room, or the use of intraoperative imaging to visually align tool and target, does not, by this definition, create an IGP.

HISTORY

Approximately 10 years after the surgery by Clayton (1), Horsley & Clarke (2) presented a device that embodied two ideas fundamental to surgical guidance: image space and physical space. For their process, known as stereotaxy, to work, both the image space and the physical space must in some way be registered, i.e. the transformational relationship between two three-dimensional spaces must be determined. In this case the image-space map consisted of anatomic drawings and sectioned samples, but it inaugurated the concept that direct surgical visualization was no longer necessary for the accurate placement and guidance of medical devices. Their concept for charting the physical space was an extracranial device, or frame. Horsley & Clarke accomplished this by mounting on a subject a frame based on intrinsic reference points, anatomic landmarks such as the external auditory canals and the inferior orbital rims. Based on these landmarks, the frame could be identically mounted on every

subject and the image-space maps could then be used to place electrodes, make lesions, and take tissue samples. There is an implied relationship here: that intracranial structures of the brain have a stationary relationship to extracranial anatomic landmarks across the subject population. That is, the general case sufficiently defines the specific. However, the fundamental problem in using this technique on humans was that the map between external anatomic landmarks and intracerebral locations proved not to be stationary across human beings.

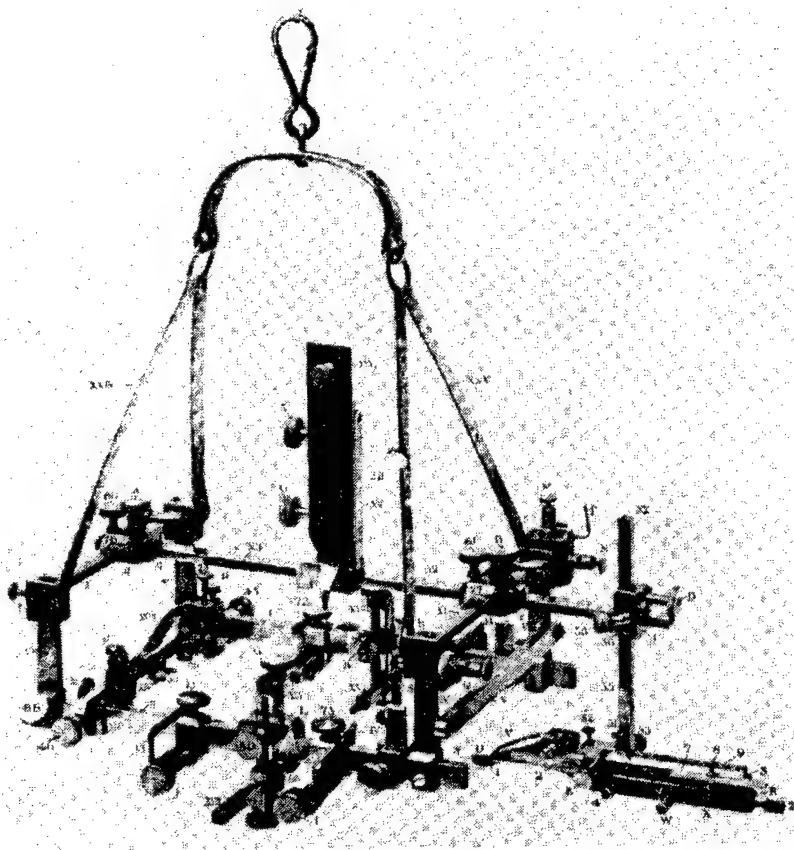


Figure 1: The Horsely and Clark Stereotactic Frame.

Thus, for accurate guidance, generalized atlases and representative tissue sections alone were inadequate.

Although stereotactic techniques have been applied to a number of different surgical areas (3--6),

stereotaxy has found its most common application in neurosurgery because of the singular structure of the cranium. The need to operate on this structure, unique in that it is a solid organ almost entirely encompassed by bone, leads to two major constraints. The first is with the protective nature of the skull. Surgeons prefer to make the minimum opening required to perform the surgery but must make a large enough opening to guarantee access to the entire site. Second, there is the functional importance of all the tissue between the

surface of the brain and the site of surgical interest. These surgical constraints have led to a desire to develop techniques for accurate location of positions within the brain prior to the opening of the skull.

The term site of surgical interest is meant to span all the applications of stereotaxy. The first, and still most-often used, application of stereotaxy was for the placement of electrodes to known physical locations for the mapping of the brain's electrical activity and functional response (7--12). The mapping process was followed by the development of surgery that attempts to change the function of the brain in some fashion. These procedures, collectively known as functional neurosurgery, differ from other forms of stereotactic neurosurgery in that there is not always a visible focus for resection, and the surgery is not to remove some lesion or vascular abnormality but to attempt to change some undesirable neurologic function. The surgical point is determined by observation of the local area's function, generally through electrical monitoring, and the correlation with known functional locations or anatomic landmarks.

In 1947, Spiegel & Wycis (13) published a paper describing their device for human stereotaxy. This apparatus did not use skull landmarks for the location of soft-tissue targets. Rather, it extracted information from pneumoencephalograms. By providing visual information as to the relationship between the stereotactic apparatus and soft-tissue landmarks, such as the foramen of Monroe and the pineal gland, electrodes could be guided with much greater certainty. By taking care to preserve well-defined geometries in their imaging, each patient's films became a specific atlas to guide electrode placement. . In addition, it is an example of the use of image information in a quantitative way. Arguably, the concept of using pneumoencephalograms and ventriculography as a mapping of the topology of the brain did not occur to Spiegel & Wycis exclusively. During the next few years, several major stereotactic systems were initiated. This included the first Leksell (14) and Riechert & Wolff (15) (later Riechert-Mundinger) systems. In France, Talairach et al (16) returned to Horsley & Clarke's electrophysiology idea by using anatomic landmarks and an atlas of function combined with patient-specific information from images to allow the placement of electrodes. Two reviews of stereotaxy can be found elsewhere (17, 18).

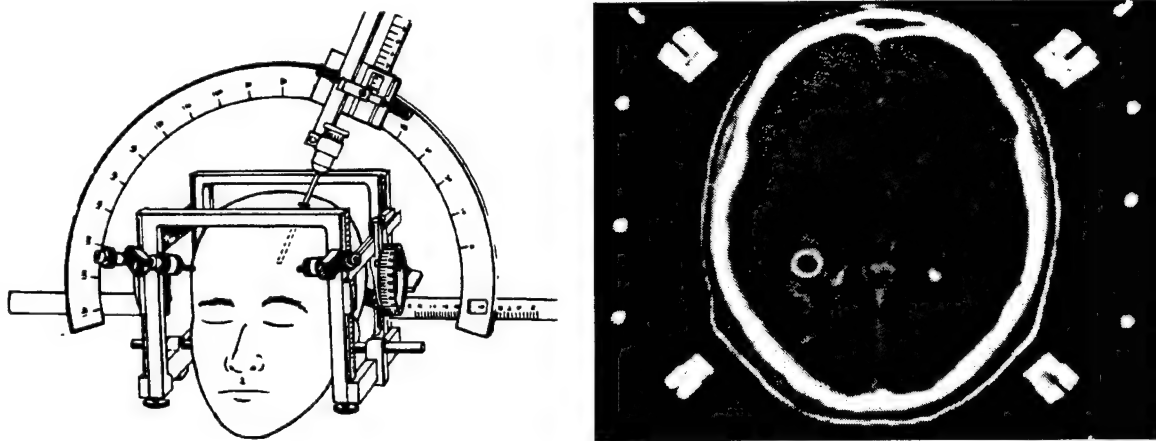


Figure 2: CT-Enabled Stereotactic Frame and CT slice showing N-Bars

With general charts proving to be unacceptable, stereotaxy had to await an improved method for determining locations within the brain. The development of pneumoencephalograms and, later, iodine-based contrast agents for ventriculography started the process of patient-specific localization. Now structures within an individual's brain could be visualized, and landmarks and distances determined for each subject. A surgeon could visualize specific anatomy in his patient. The use of radio-opaque materials for constructing the frame allowed it as well structures within the brain to be seen in the images. But the pneumoencephalography/ventriculography technique was not without its drawbacks. Because both types of images are shadowgrams, or projection images, they compress information about a three-dimensional object onto a two-dimensional plane. If a point could be uniquely determined in both anterior-posterior and lateral films, then a probe could be guided to that point by a series of frame adjustments. The ability to exactly define the point of surgical interest in both films was in no way guaranteed. In the absence of exactly definable points, the surgeon's experience and knowledge of general anatomy could help approximate the site of surgical interest, the general case combined with specific information helping to better approximate the individual case. If the target were visually or electrically distinguishable from the rest of the anatomy, then the site's location could be refined from the rough position determined by the frame. The conceptual breakthrough was

that the ventriculogram provided surgeons with patient-specific information to modify their three-dimensional understanding of general neuroanatomy.

Once localization and targeting techniques had been developed, stereotactic methodologies were invented for a variety of therapeutic procedures. As was the case with the electrode placement, therapeutic protocols followed protocols designed to gather information. Once it had been shown that a narrow-gauge needle could be placed at the tumor site with relative accuracy, local radiation therapy by the stereotactic placement of radiation sources became possible (19, 20). Currently, there is an array of different radioactive materials that may be placed at the target site (21--24). To some degree, different materials are selected for different tumor types, so the biopsy procedure often precedes placement. Recently there has been an expansion of interventional efforts to place therapeutic objects directly in the lesion. These include controlled release chemotherapy agents (25).

To accurately assess the efficacy of chemotherapy and radiation therapy protocols for deep-seated tumors, histologic confirmation of the neoplasm type is needed. Furthermore, biopsy may be pivotal in the selection of the most appropriate course of treatment. Surgical biopsy by craniotomy subjected patients to most of the risks of surgical resection. Stereotactic biopsy was developed as a greatly less-invasive procedure for capturing tissue for histological examination (26--30). Once the neoplasm type is exactly defined, then the most appropriate form of therapy can be prescribed.

Along with resection, in which tissue is removed from the brain, stereotaxy can be used in transplanting tissue into the brain. The transplantation of adrenal medullary tissue into the brain for the alleviation of Parkinson's disease symptoms is a surgical procedure of both great promise and great debate (31--33). One factor that has led to the uneven success among various sites is the variability of the implant location. Stereotactic techniques can be used to control that variability, helping to place implants of glandular tissue in specific, consistent locations, thus reducing the risk of the procedure. Stereotactic techniques were also developed for external beam radiation. In 1951, Leksell (34) introduced the concept of radiosurgery, i.e. the use of targeted external beam radiation, in which the dose delivered to the target is built by the summation of beams from a variety of angles. This method allows a greater dosage to be delivered to the target while reducing that to the rest of the tissue.

Modern tomographic methods have allowed better definition of tumor margins, and new techniques for intensity-modulated radiation therapy allow for the "sculpting" of the delivered dose (35, 36).

ADVENT OF IMAGE-GUIDED PROCEDURES

The creation of computed tomography (CT) provided the surgeon with a three-dimensional, patient-specific atlas. Although a number of researchers used this new technique with frames (37--40), and techniques were developed to merge CT and plane film data (41), the availability of three-dimensional data coupled with a rapidly advancing computer field made new approaches possible. In the mid to late 1980s, a number of researchers began to develop systems that, although varying greatly in implementation, shared a common revolutionary idea: track the surgical position in the physical space and display position in image space. This constitutes a reversal of classic stereotaxy, in which the physical location is determined from the images. Dubbed frameless stereotaxy by some (42--44) and interactive, image-guided neurosurgery by others (45, 46), the process had three major components:

1. A three-dimensional spatial localizer. This device could be freely moved in the operating room, and the location and trajectory of its tip dynamically tracked. Thus, the device would return a position triplet $\langle x_p, y_p, z_p \rangle$ for the space defined by its motion.
2. A registration technique. As with previous stereotaxy, the relationship between the space defined by an extracranial device and locations seen in the image space $\langle x_i, y_i, z_i \rangle$ must be determined. Instead of mapping image location into frame adjustments, $\langle x_i, y_i, z_i \rangle \Rightarrow \langle x_p, y_p, z_p \rangle$, the localizer position is mapped into image space $\langle x_p, y_p, z_p \rangle \Rightarrow \langle x_i, y_i, z_i \rangle$ and that point is displayed on the appropriate image or images. This means that all image information is retained and dynamically displayed as the surgeon moves the localizer. Thus, surgeons are able to determine not only their present surgical position but the position of all perceptible anatomic structures.
3. A means of displaying the location in image space. The timing of the development of systems that tracked surgical location in image space was not accidental. Computers capable of storage, recall, and display of large medical image sets,

and yet of a size and cost appropriate for operating rooms, were not available until the 1980s.

The first system in press was the tracked microscope system of Roberts et al (47, 48) from Dartmouth, followed quickly by a system developed in Tokyo (49, 50). It is appropriate that the first two systems used two distinctly different methods for surgical location. The Dartmouth system used a sonic triangulation method for localization whereas the Tokyo system used an articulated arm. Those two approaches represent the dominant three-dimensional localization paradigms, as explained below.

FUNDAMENTALS OF IMAGE-GUIDED PROCEDURES

IGPs have four basic components: image acquisition, image-to-physical-space registration, three-dimensional tracking, and display of imaging data and location. In addition, some registrations and displays require segmentation techniques.

Image Acquisition

IGPs require dealing with five different types of images:

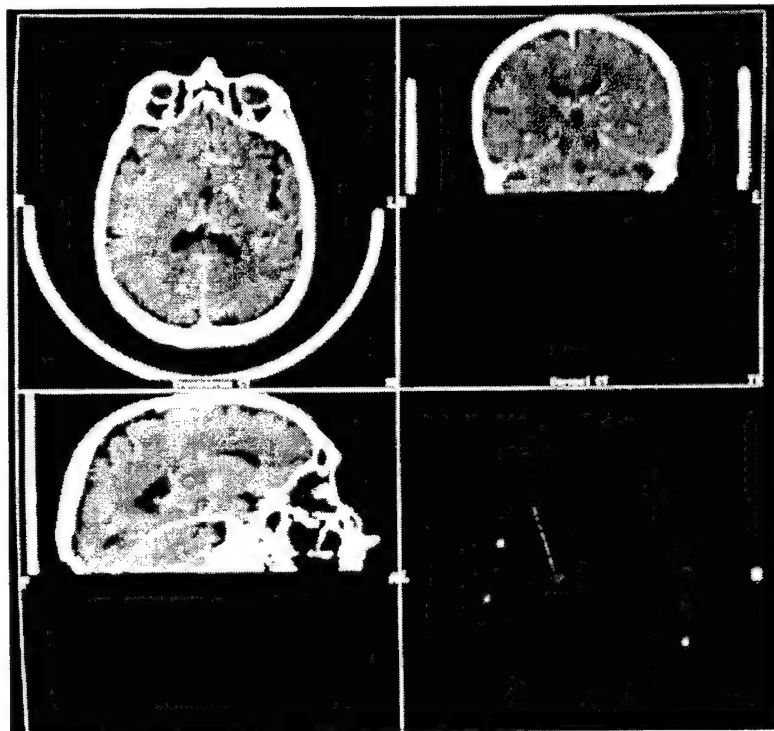
1. Projective images such plane films and angiograms; tomographic sets such as computed tomography (CT), magnetic resonance imaging, (MRI), and emission tomograms (SPECT, PET).
2. Intraoperative two-dimensional imaging; ultrasound image, which creates slices but which a number of researchers are combining into volumes.
3. Laparoscopic, endoscopic, and microscopic images, which are projective and may have distortions; . intraoperative plane film imaging, which both projective and has distortions associated with the image intensifier.
4. Intraoperative tomograms, including both CT and "open-frame" or "therapeutic" MRI.
5. Processed images, including rendered images that may represent an extracted anatomic surface, and images such as maximum intensity projections from tomographic angiograms.

Although the history of stereotaxy is dominated by projection images, in IGP they are rarely used. This is due to two issues. First, in order to form a registration, six reference points (fiducials) are required to be located in image space and physical space. Tomograms

require only three to be found (51, 52). Second, a projective image has significant spatial uncertainty in the third dimension.

At Montreal Neurologic Institute, there is a history of the acquisition and use of stereo pair angiograms (53). This history carried over into the stereotactic and IGP system developed there (54, 55). By obtaining stereo images, the depth uncertainty can be reduced. That simultaneously obtained projection images can reduce spatial uncertainty has also been shown with "C-arm" intraoperative imaging and fluoroscopy (56). The pincushion and S distortion in the image intensifiers can be corrected (57), and if homologous points can be unambiguously identified in both images then the point can be identified in three dimensions.

Tomographic scans have been used since the initial development of IGP. Both Roberts et



al (47) and Watanabe et al (49) displayed surgical position on a single tomogram slice.

Galloway et al (58) demonstrated a four-window display (each 512 x 512 pixels) with image sets selectable from various tomographic modalities. These images could be displayed in the native orientation, or

reconstructed sets in the other cardinal planes could be shown.

Figure 3: Cardinal plane view.

Guthrie (59) and Smith et al (60) developed systems in which the original image volume was resliced to show the plane perpendicular to the surgical trajectory. Perhaps the first real demonstration of the power of using modern tomographic sets quantitatively was in a

surgery performed to separate conjoined twins (61). Here the data was used not only for qualitative assessment and point localization, but also for distance, surface, and volume determination. Although these results were not directly linked to the procedural guidance, the success of the procedure demonstrated the true value of image analysis, image processing, and data extraction in guiding a therapeutic process. These processes allowed the determination of the volume of shared tissue, the amount of skin needed for grafting and allowed surgeons to simulated different approaches and resection strategies.

There are two major difficulties of using preoperative tomograms as an exclusive form of guidance. The first is that the tomogram requires that the surgeon look up from the surgical view and blend it with the tomographic orientation. This difficulty has been addressed in a number of ways. In 1993, a concept called enhanced reality was pioneered, in which rendered objects from a tomographic data set were projected into the surgical viewpoint and blended into the visual display (62, 63). This concept was furthered by injecting that blended image into an eyepiece of a surgical microscope (64). There are significant challenges to these systems in terms of not overwhelming the visual system of the viewer.

Mainwaring (65) pioneered a different approach, in which a tracked endoscope serving as a surgical pointer had its position displayed on a computer monitor. By placing the computer monitor showing the tomographic position next to the video monitor showing the endoscope images, the data from each could be merged. Stefansic et al (66, 67) have shown derivative systems in which the video images replace one of the windows in a four-window display. A related but distinct approach uses an image set derived from a tomogram set. In virtual endoscopy (68, 69), a tomographic set of anatomical structures able to be traversed by endoscopes is segmented and rendered in such a way that a path mimicking that of an endoscope can be followed. This has the advantage that, unlike with a true endoscope, it is possible to see "beneath" the surface of the tissue of the traversed structure. Such a virtual endoscope is also able to get past blockages that may foil a true endoscope. However, such displays cannot provide the visual clues as to whether tissue is healthy or not. Therefore, the combination of virtual-endoscopy and true-endoscopy images retains the power of both methodologies (70, 71).

Three-Dimensional Localization Systems

Localization technologies can be divided into three classes: geometric, triangulation, and inertial. Although there have been some attempts at using inertial systems for surgical localization devices, currently such systems are unwieldy. The primary confounding property of the localization task is that it is actually a six-dimensional task. To be of real use, not only the X, Y, and Z axes but also the spatial orientation of a device must be tracked. These orientations can be represented as yaw, pitch, and roll. Certain geometric techniques, such as placing the device tip along a device axis, can reduce the problem to five dimensions, but for inertial systems that still means five gyroscopes or gyroscope-equivalents.

Thus, the field of localizers can be reduced to two classes of devices: geometric and triangulation. As mentioned above, these two classes were represented by the first two IGP systems, the Dartmouth and Tokyo systems. Geometric localizers use angle, extension, and/or bend systems to sense the position of the procedural device. Articulated arms using potentiometers or optical angle sensors are the most common. Beyond the Tokyo system, researchers from the University of Aachen (72), Vanderbilt University (73), the University of Oulu (74), the University of Alabama-Birmingham (75), and Henry Ford Hospital (76) all developed systems using articulated arms. In addition, one of the first commercially available systems from ISG used an articulated arm made by Faro (Faro Technologies, Lake May, FLA) (77).

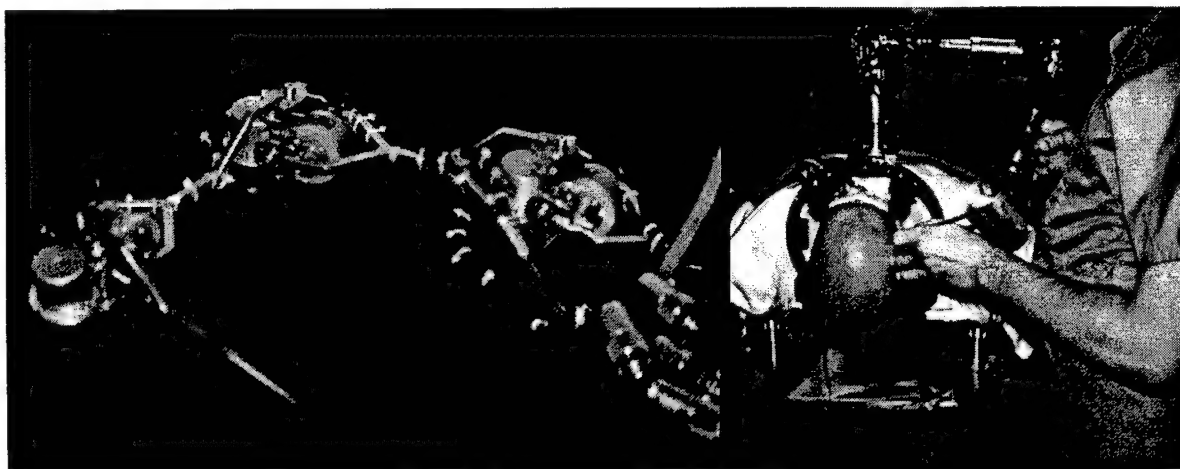


Figure 4 – The two Vanderbilt Articulated Arms

Articulated arms suffer from one major problem as surgical localizers: In order to be accurate, they must have stiff arms between the rotational joints. That requirement limits how light the device can be. And although counter-weighting can make the device's end effector seem to float, such techniques add to the mass and, thus, to the inertia of the device. It is because of this constraint that most developers have moved away from articulated arms as surgical localizers. They may yet have applications in nonsurgical IGPs, such as positioning patients for radiotherapy.

Although the use of articulated arms is on the wane for image-guided surgeries, there is a growing application for another geometric localization technology. In a number of therapeutic procedures, for example otolaryngology and colon polyp biopsy and treatment, it is difficult or inappropriate to use rigid instruments. Technologies such as the Shape Tape™ allow the tracking of curvature and thus the end point of the devices (78). Although the accuracy of such systems is not what it needs to be for IGP, active development is under way.

The second major type of localization systems used in IGP is triangulation. In these systems, an emitter or emitters broadcast energy to a series of detectors at known locations. By measuring the distance or angular position of the emitters, the emitter's location can be determined. If three or more emitters are mounted on a rigid structure, then the location and orientation of that structure can be determined.

In the pioneering work done at Dartmouth (48) and then in later work done at the Cleveland Clinic (79), the triangulation systems were sonic. They consisted of emitters mounted to the microscope (Dartmouth) or to a bipolar cautery device (Cleveland Clinic). In both systems, multiple spark-gaps were used as a sound point source and the time-of-flight (TOF) between source and detector was measured. From this the distance was determined and the location triangulated. The acoustic systems had two problems, both related to the speed of sound. Variations in the speed of sound led to errors in the determination of the emitter location and, thus, the object's location. This could be handled by a method called pilot sparking (80), in which a fixed spark gap was fired periodically and variations in transit time were used to correct for changes in the acoustic propagation velocity. The second, and more intractable, problem was that of TOF. In the time from the first event to the last, the

device cannot move or a serious localization error will occur. Therefore, the device must remain stationary for $N(\text{TOF} + \text{TD})$, where N is the number of emitters and TD is the timing delay between spark events necessary to deal with reverberations. If you presume an average emitter-detector distance of 2 m, then the TOF from each emitter to the detector (in STP air) is 6 ms. This requires a stationary tracked object and limits update rates and numbers of emitters, thereby making the device sensitive to shadowing (81). Shadowing occurs when the handle of the device lies between the emitters and the detector, thus blocking localization.

The TOF issue vanishes if the ultrasound energy is replaced by electromagnetic energy. With electromagnetic sources, TOF and TD effectively become zero replaced only by source and detector time constants. This means that in directional sources, such as optical sources, the number of emitters can be high, allowing for full range of motion without object shadowing. If the electromagnetic emitters are radiofrequency (82) or magnetic (83, 84), which are effectively omnidirectional, then the only limitation on the number of emitters is their size.

Optical devices, both active (84--86) and passive (87--89), currently dominate the IGP field. This is perhaps surprising, given the need for a continuous line of sight and the directional restrictions of the optical emitters that either force a large number of sources or limit the orientation of the tracked device. However, optical methods may be winning by default. The surgical suite contains large, conductive structures, such as the operating table. Because of the motion of tools and conductive fluids, and the presence of electrically active devices, such as abalators, imaging devices, and patient-monitoring equipment, it is a dynamic, conductive environment. All these factors have been shown (90) to confound radiofrequency and magnetic localizers. Active work continues on magnetic localizers (91), especially for tracking devices in closed patient situations.

REGISTRATION

Three-dimensional localization and tracking devices determine position in physical space. In order to use that information quantitatively with image data, a registration from image space to physical space must be performed. There are three classes of registration techniques: point based, feature based, and volume based. Of the point-based registration,

there are two subtypes. The first uses anatomic landmarks or features as intrinsic reference points, or fiducials. The second requires the attachment of extrinsic objects, or fiducial markers. The differences between marker-based and feature-based registration are relatively clear. Because the markers must be in place prior to the acquisition of images, the decision to use marker-based registration must be made before acquisition. For this reason, marker-based registration is said to be a prospective method. In contrast, feature-based registration can be retrospective, meaning that the decision to perform registration can be made after the image sets are acquired. However, feature-based registration, in general, requires more computation than do marker-based methods, and they are prone to larger error (92). In addition, it is difficult to determine the quality of a registration arising from a feature-based registration. In contrast, there are statistical methods for estimating the quality of a marker-based system.

Point-Based Systems

In point-based systems, points are localized in both image space and physical space. The locations of these landmarks in the two spaces can be arranged as lists of three-dimensional coordinates and a three-dimensional transformation between the two sets determined by any one of a number of mathematical methods (93). In the early image-guided surgery systems, anatomic landmarks, such as the nasion, the tragi, and orbital rims, were used as intrinsic fiducials (49, 77, 94). There are significant difficulties with this approach. It is difficult to define an anatomic point, and even could such a point be located in physical space, the averaging effect of finite-slice thickness introduces a spatial uncertainty. Evans et al (95) demonstrated that by overdetermining the problem, e.g. by localizing more points than the minimum number necessary to determine the transformation (three for three-dimensional images), they were able to produce transformations that were more robust to errors in the localization of any given point. However, if the localization errors among markers or features are uncorrelated, then overdetermination, as, for example, in Evans's approach, can be employed to attenuate the effect of those errors on the calculated transformation.

The benefit of increasing the number of homologous points leads to a challenge in the use of anatomical landmarks. The reason that images of a patient are acquired in multiple modalities is that they provide distinct information. Therefore, almost by definition, it will be difficult to accurately locate a large number of homologous anatomic landmarks in multiple

sets. In fact, as the number of modalities increases, the ability to find the same anatomy in each decreases dramatically. Furthermore, in a given modality, the $N + 1$ landmark can always be expected to be more difficult to localize than the N landmark.

In physical-space localization, these same problems arise. As with image localization, if the localization errors are uncorrelated, they can be minimized by overdetermination. However, in attempting to localize significant numbers of points, it quickly becomes difficult to continue to determine structures that can be adequately localized in both image space and physical space. Significant work has gone into using landmarks on the upper row of teeth (96), but they are poorly visualized on MRI and not at all in positron emissions tomography.

The need for large numbers of landmarks arises because of the difficulty of accurately localizing a single landmark. An alternative approach is to construct a landmark, or "marker," that is designed specifically for accurate localization and then to attach it to the patient. Such markers are termed fiducial markers. In using anatomic landmarks as fiducials, researchers attempted to use them as intrinsic reference points. The difficulty is that there are very few anatomic points, and even in those structures that might come to a point, the partial volume effect of tomographic imaging blurs their location into a voxel-sized resolution cell. The difficulty is that the user has only general apriori knowledge about the object he or she is attempting to localize. This handicap severely limits the mathematical tools that can be brought to bear to improve spatial localization to less than a voxel size. However, if there is knowledge about a structure and understanding of how the imaging process works, then the object can be localized in space to a much higher accuracy.

Most researchers developing systems for IGPs have used extrinsic fiducials at some time. Common early practice included surgical staples or small ball bearings for CT (97, 98) and capsules filled with oil or fat for MRI (99). However, the staples caused slight star artifact in CT, making it difficult to localize a part of the staple for use in identification in physical space, and the center of the ball bearing, although easy to localize in image space, was difficult to localize in physical space. The oil-filled and fat-filled capsules exhibited chemical shift of up to 1 cm in the MRI unit, making them inappropriate for localization tasks (100).

As the concept of extrinsic fiducials grew, the physical objects (fiducial markers) that embodied the fiducials became more sophisticated. The markers could be made to be visible in multiple image modalities, and the mechanisms by which physical space localization was accomplished increased in accuracy. From simple, in-house--created objects to commercially developed and marketed marker systems, a number of fiducial markers are available. In general, they break down into one of two classes: skin-surface attachment or bone-implanted markers. The division between the classes is clear: Skin-surface markers are much less invasive than bone implant markers, but the skin-surface markers contain a potential source of error due to skin motion. This motion may be normal to the skull surface, due to skin swelling or skin drying, or it may be tangential, due to tractions, such as placing the head in a Mayfield head clamp prior to surgery (101).

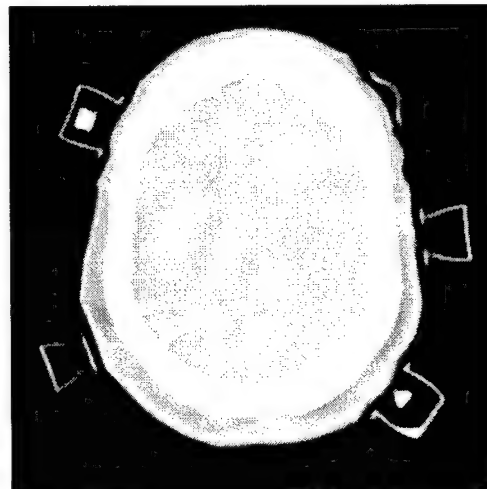
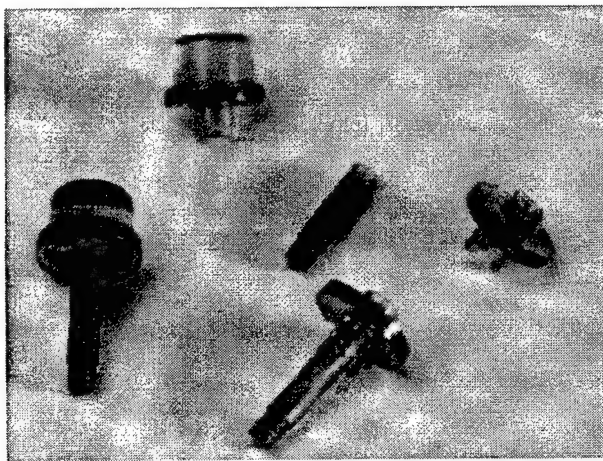


Figure 5 – Acustar markers and CT showing Marker

There are two commercial realizations of bone-implanted markers: the Acustar system, developed by Vanderbilt University and Johnson & Johnson Professional Inc (102), and one developed by Leibinger (103), now a part of Stryker Inc. Implantation of the bone-implant markers is analogous to minor dental surgery. The skin surface is cleaned, and a local

anesthetic is applied to the scalp. A small incision is made, and the marker posts are screwed into the outer table of the skull. In the case of the Acustar markers, a flat-bottom hole is drilled and the mounting post screwed into the hole. In the case of markers from Leibinger, the markers mount on a self-tapping titanium post that is screwed into the outer table of the skull. The Acustar imageable markers are cylinders, 7 mm in diameter and 5 mm high, filled with a water solution containing iodine and gadolinium, designed to be visible in CT and a wide range of MRI sequences. The size guarantees that at any orientation, the marker is visible in more than one tomogram slice of thickness less than 5 mm. To date, these markers have been tested with T1-, T2-, and proton-density-weighted spin-echo sequences, as well as magnetic resonance angiography and gradient-echo images, and they are accurately localizable in all of them (104). The Leibinger marker system consists of a titanium screw, a base component, and an imaging marker. The imaging marker has a 2-mm-diameter spherical volume, which can be filled with a contrast agent. A more complete review of markers is available in a paper by Fitzpatrick & Galloway (105).

Feature-Based Systems

The retrospective nature of the use of intrinsic features continues to appeal. Although difficulties in identifying anatomic points remain, by localizing surfaces or features, the need for one-to-one correspondence is removed, and the use of a large number of points creates an averaging effect that reduces uncorrelated localization noise. A number of researchers have tried to use skin-surface information, both by contact (106) and by optical means (107, 108). The problem with these techniques is that the skin surface is a dynamic structure, responding to both preoperative drug regimens and intraoperative tractions. For the head, this problem has been addressed by using the skull surface as a registration feature, capturing intraoperative data by use of a tracked A-mode transducer to localize the skull surface transcutaneously (109). Others have used features on the brain surface for intraoperative registration (110, 111). However, the brain changes shape once the skull is opened, with the greatest changes being at that opening (112).

For applications other than intracranial, surface information has been used more successfully. Two groups (113--115) have examined surface registration in the spine, either by touching points on the vertebral surface or by tracked, transcutaneous ultrasound. In

addition, two groups have used the organ surface in liver surgery (116, 117). A point-based registration is usually used to provide an initial estimate for the surface registration.

The most common algorithm for matching a cloud of acquired points and a derived surface is the ICP (iterative closest point) (118). One intriguing aspect to this method is that a mix of surface and point features can be used. Maurer et al (119) demonstrated that by using such a mix, a better registration can be obtained than by using points or surfaces alone.

Volume-Based Systems

Although volume-based registration has proven to be the best of the retrospective image-to-image methodologies (120), volumetric registration for image-guided therapy has proceeded slowly. The issue here is that if a high-quality intraoperative volumetric data set can be acquired, why use preoperative data at all? In certain specialized applications, such as therapy for prostate cancer, three-dimensional intraprocedural ultrasound can be matched to preoperative tomographic data on which therapy preplanning has occurred (121).

APPLICATION EXAMPLES

As stated at the beginning of this article, IGPs grew out of stereotaxy, driven by both the functional importance of tissue surrounding the site of surgical interest and the presence of the skull, which serves as a static mechanical platform for the soft-tissue target: the brain. However, IGPs were not merely improved stereotaxy, they opened the way for new modes of thinking about therapy delivery. The importance of specificity, of treating the lesion completely with as little damage to healthy collateral tissue as possible, came to the forefront. With the parallel development of minimally invasive techniques in other fields, we are beginning to see a convergence, with IGP being used for abdominal, spinal, and other form of therapy.

Intracranial Resection/Ablation

Given the preponderance of intracranial neurosurgery and otolaryngological applications described earlier, it would take an article much bigger than this to cover the clinical applications of IGP in the head [for more complete references see (122--125)]. However, it is here, where the field is most mature, that the results of the first generation of work and ideas for the second generation can be seen. For cancer cases, the ultimate assessment is, do

the patients have better outcomes with IGP than with previous methods? Perhaps the best data for that comes from the work done by Berger and coworkers (126, 127). In their papers, significantly better outcomes are demonstrated using resections to imaging defined margins as opposed to visually defined margins.

In addition, the presumption that tissue is rigid has been discarded, and mechanisms for correcting for periprocedural tissue deformation are coming on line. These include biomechanical models of the tissue (112, 128, 129) and the use of intraoperative ultrasound imaging to gather information for the correction of preoperative, high signal-to-noise images (130, 131).

In emerging image-guidance systems, we are beginning to see functional mapping play a greater role than in first-generation systems, in which all guidance has been done by anatomic image sets. The functional information is coming from positron emissions tomography, functional MRI, and "superbrain" image sets in which a functional atlas is defined. In the case of the atlas, it is nonrigidly registered to the patient's image set. The resulting deformations can then be applied to the functional data, providing a probabilistic functional map of the patient. It is in the placement of deep brain stimulators that this work has shown the most growth.

Beyond purely surgical intervention, IGPs have been used to place controlled-release chemotherapy agents in brain tumors (132), and there has been discussion of using these techniques for placement of gene therapy agents to improve their efficiency (133).

Although cancer therapies have dominated the intracranial applications, IGPs have had a role in vascular surgeries (134, 135), and image-guided radiosurgeries for vascular abnormalities have become commonplace (136, 137).

Functional Neurosurgery and Stimulator Placement

The use of electrophysiological data for guidance goes back to the beginning of stereotaxy. Interventional applications, such as ablations of foci of abnormal electrical activity for interruption of epileptic seizure initiation or propagation (138, 139), and ablations of deep gray nuclei for alleviation of Parkinson's disease tremors (140, 141), used imaging to approximate the ablation site but used electrophysiological recording for final guidance. Additionally, ablations have been performed for the relief of chronic, previously intractable pain, such as that arising from some forms of cancer (142, 143). However, such techniques

were limited by the variability of anatomy, distribution of function, and presence of space-occupying lesions. However, two recent developments are spurring additional growth. The first is the use of implantable stimulators to act as reversible ablations (144, 145). This means that cellular disruption need not be a permanent step. The second advance is the use of image volumes as atlases to allow the better integration of data across patients (146, 147). In addition, the use of functional MRI as a data source for IGPs promises to provide patient-specific functional information. However, continued work is needed to fully understand the fMRI images and to validate their use. Beyond surgical ablation and the placement of stimulators, image-guided radiosurgery (148) has found applications in functional procedures.

Spinal Applications

Over a quarter of a million lumbar spine operations will be done in the United States this year. The federally funded Back-Pain Patient Outcomes Assessment Team (HS 06344) placed the cost of back pain, the leading cause of loss of work days in the United States, at \$50 billion. Beyond the lumbar problems, cervical spine fractures and cystic, vascular, and neoplastic diseases of the spinal cord add a significant number of cases each year. The nature of the spine represents a substantial challenge for image-guided techniques. The spine cannot be presumed to be monolithically rigid; rather, it is piece-wise rigid, with deformable structures between the rigid segments. This requires a system in which multiple registrations can be performed. Beyond the vertebral and disk structures, the spine is a web of ligaments and tendons with intertwined vascular structures and functionally vital nerve roots. The challenge is so complex that in 1999 a workshop was held to try to clarify the technical requirements for image-guided spine procedures (149).

One of the leading sources of failure in surgery to alleviate pain or structural failure is the change in the length and mechanics of the spine following surgical intervention. A recent advance in the use of struts called spinal instrumentation is replacing direct vertebral fusion. Often, to rigidly attach the instrumentation, the device is fixed to the vertebrae via the use of screws driven into the pedicle of the vertebrae. Because the spinal cord, nerve roots, and supporting vasculature all lie within millimeters of the pedicle, accurate guidance is essential. Image-guidance techniques using preoperative tomograms and intraoperative imaging such as dual fluoroscopy have been developed (150, 151).

Although tumors of the spine represent a lesser health care issue than does back pain or trauma, the occurrence is devastating to the individual. IGPS both surgical (152, 153) and radiosurgical (154) are showing promise for more specific resection.

Orthopedics

Although neurosurgical applications were driven by the functional importance of intervening tissue between the skull and the lesion, orthopedic applications were driven by the need for accurate and precise control of position and angle. It is the need for precise positioning of position and angle that opens the doors for robotic IGPs. Although robots have been used in surgery for a while (155, 156), their role has been essentially device holder. The Robodoc system (157, 158), with an active head, is essentially an image-guided, numerically controlled milling machine. This allows the very accurate and precise placement of artificial hip components both in the femur and on the pelvis. Beyond hip replacement procedures, additional orthopedic applications include use in acetabulature fractures (159) and in osteotomies (160).

Abdominal

As IGPs prove their worth in intracranial, spinal, and orthopedic applications, their potential value in abdominal surgeries becomes more apparent. Two of the early targeted areas have been the liver and the prostate. In both, the major challenge is registration. Unlike the skull, the vertebrae, or the long bones, in liver and prostate there can be no presumption of even piece-wise rigidity.

In liver surgery, intraoperative ultrasound has become the standard for image guidance (161, 162). However, ultrasound is a low signal-to-noise imaging modality, and it is difficult to localize the center of a three-dimensional target. Recent work (163, 164) is bringing three-dimensional localization and guidance into liver surgery. Additionally, image-guided cryosurgery (ablation of tissue with extreme cold) (165) and interstitial photon radiation therapy (166) have been applied to the liver.

Prostate cancer is one of the most commonly occurring forms of cancer, and new blood chemistry studies have increased the detection rate of that cancer. However, optimum treatment remains difficult. Transperineal approaches have been developed, but patient posture and bladder fullness can cause significant changes in prostate position and

orientation. Intraprocedural imaging, such as transrectal ultrasound (167--169) and intraprocedural MRI (170), have helped improve guidance. Interstitial brachytherapy (169, 171) has been shown to be effective and relatively safe. However, techniques need to be developed to correct for changes in the prostate during brachytherapy seed placement (172) and for deflection of the radioactive seed placement needle.

CONCLUSIONS

Although there has been an explosion of interest in image-guided procedures (IGPs) over the past decade, and a single review article is defined as much by what it leaves out as what it contains, we are still very much in the first generation of IGPs. For the most part, we deal with tissue as if it is monolithic and rigid, we guide procedures based on anatomy rather than function, and we are crudely integrating image information over time and space. The biggest question, do IGPs produce better outcomes, is only now being addressed. However, there are some signs that we can point to. Once implemented on a regular basis, IGPs take less operating room time than do equivalent stereotactic procedures (173), IGPs are rapidly being integrated with minimally invasive procedures to reduce patient discomfort and recovery time (174), and IGPs are enabling technologies, allowing the possibility of successful treatment where it was not possible before.

Having demonstrated that image-guided procedures can be made to work and having some evidence that they have positive clinical outcomes, considerable effort needs to be placed into validation and assessment of systems and techniques. One of the difficulties is comparing published results of IGP's is that system performance is not measured in a consistent manner. For example, some users of localizers report precision where some report accuracy. There is, as of yet, no satisfactory way to assess the accuracy of a surface-based registration using only the two sets of surface points. The field needs independent assessment measures perhaps developed through the National Institute for Standards and Technology. If these tests can be developed and agreed upon, then when a new technology or process emerges, it can be assessed on a level playing field.

The maturation of IGPs requires a change in research teams as well. Any system where the design engineer presumes to understand a procedurist's needs and builds a device to those standards is doomed to failure. Correspondingly, the field has demonstrated that a

successful device or process requires a level of technical sophistication beyond that of physicians working on it in their spare time. Successful creation, development, and refinement and appropriate testing of IGPs is going to require teams of physicians, engineers, computer scientists, nurses, and clinical trial and outcome experts. However, the potential payoff is enormous. By guiding therapy to where it is needed, and by avoiding healthy structures, both the process and the outcome are improved.

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Image-guided Surgery and Therapy: Current Status and Future Directions

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ABSTRACT

Image-guided surgery and therapy is assuming an increasingly important role, particularly considering the current emphasis on minimally-invasive surgical procedures. Volumetric CT and MR images have been used now for some time in conjunction with stereotactic frames, to guide many neurosurgical procedures. With the development of systems that permit surgical instruments to be tracked in space, image-guided surgery now includes the use of "frame-less" procedures, and the application of the technology has spread beyond neurosurgery to include orthopedic applications and therapy of various soft-tissue organs such as the breast, prostate and heart. Since tracking systems allow image-guided surgery to be undertaken without frames, a great deal of effort has been spent on image-to-image and image-to-patient registration techniques, and upon the means of combining real-time intra-operative images with images acquired pre-operatively. As image-guided surgery systems have become increasingly sophisticated, the greatest challenges to their successful adoption in the operating room of the future relate to the interface between the user and the system. To date, little effort has been expended to ensure that the human factors issues relating to the use of such equipment in the operating room have been adequately addressed. Such systems will only be employed routinely in the OR when they are designed to be intuitive, unobtrusive, and provide simple access to the source of the images.

Keywords: Image-guided surgery; image-guided therapy, registration, tracking, robotics, virtual reality, simulation, software

1. INTRODUCTION:

Image-guided surgery and therapy has its roots in the field of stereotactic neurosurgery. While this approach was not specifically "image-guided" in the beginning, it nevertheless provided the means to introduce probes into the brain at precisely defined locations. At the advent of truly three-dimensional imaging, first with CT and later with MRI, volumetric images were used with stereotactic frames to guide many neurosurgical procedures. Upon the development of systems that permitted surgical instruments to be tracked in space, image-guided surgery began to include the use of "frame-less" procedures, and the application of the technology spread beyond neurosurgery to include orthopedic applications and therapy of various soft-tissue organs such as the breast, prostate and heart.

This paper begins with an overview of stereotactic technology and follows with examples of applications in common use or in development. Current problems and limitations of current practice are identified, and the paper concludes with a glimpse into the future of image-guided surgery.

2. STEREOTACTIC SURGERY

2.1 Frame-based

Computerized planning systems made their debut in the early 1980's with simple programs that established coordinate systems in the brain based on frame-based fiducial markers. This approach rapidly evolved to allow images from multiple modalities to be combined so that surgical planning could proceed using information from a combination of MRI, CT and angiographic images. Such multi-modality imaging was considered important for certain procedures, such as the insertion of probes or electrodes into the brain. The ability to simultaneously visualize the trajectory with respect to images of the blood vessels (either using orthogonal projections or stereoscopic image pairs), enabled the pathway to be planned with the confidence that it traversed within a vascular-free zone.^{1,2,25,26} Much of stereotactic surgery was concerned with procedures involving the introduction of probes, cannulae or electrodes into the brain. However, in 1986, Kelly³⁻⁵ proposed an innovative approach, based on stereotactic principles for the treatment of tumors. Instead of a narrow cannula, he approached a tumor volume via a cylindrical retractor integrated with a stereotactic frame. Such tumors could be stereotactically biopsied and treated by implantation of radionuclide sources, or resected using computer-assisted stereotactic laser microsurgical techniques. Kelly's work was a bridge between conventional frame-based stereotactic neurosurgery, and the frameless approaches that subsequently evolved.

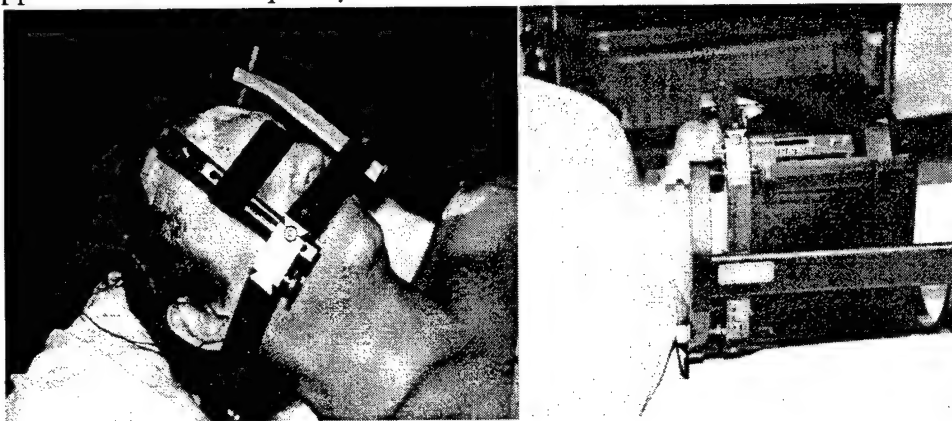


Figure 1. Typical Stereotactic frame. a) fastened to the patient's head prior to surgery; b) with fiducial marker plates attached prior to the scanning procedure.

2.2 Frameless stereotaxy

In spite of the advantages of the stereotactic frame, most involve a surgical procedure to fasten them to the patient, either through the creation of 3-4 1-2 mm deep holes in the skull with a twist-drill to accept blunt pins, or sharp pins applied to the skull under pressure. The frame (or in some cases just the

base-ring which can be separated from other structures) may also present unnecessary clutter in the operating room. Hence, there is a general desire to be rid of the frame if possible. However, without the frame to provide the fiducial markers, some other sort of reference system must be employed to register the patient to the image(s). Commonly used registration methods are discussed below.

2.3 Point matching

The most common method of registering an image to the patient involves the identification of common landmarks both in the images and on the patient. For example, a tracked pointer may identify landmarks such as the outer canthi of the eyes, the tragus of the ears, and the nasion, while these same structures are identified within the three-dimensional images of the patient. Unfortunately there is bound to be some variation in the identified locations of the landmark points on the patient, as well as some difficulty in identifying exactly the same locations within the patient's three-dimensional image. Generally, a least-squares approach is used to obtain an approximation to the correct registration. However, unless all of the

registration points are appropriately distributed about the surgical site, small inaccuracies in registration in the region containing the homologous points can be magnified for more remote points.⁶⁻⁷

2.4 Surface matching

Some systems employ a surface-matching approach to complement the point matching method. This technique involves using the probe to sample points on the surface of the patient, and then determining the best match of this point-cloud to an extracted surface from the 3-D patient image. This combined approach using both points and surfaces is described by Maurer⁸ and is incorporated in several commercial image-guided neurosurgical systems. Under ideal conditions, (i.e. in phantom tests where homologous structures are easily identified and there is no movement of the markers with respect to the object), accuracy approaching that of stereotactic frames can be achieved.⁹ However, under clinical conditions, where natural features on the patient's skin are identified, the accuracy obtainable from his type of approach decreases due to the subjective identification of homologous point-pairs on the patient and in the images. While this may be adequate for many neurosurgical purposes, it is not appropriate for procedures requiring great precision.

2.5 Bone-mounted markers

The accuracy and precision of point matching procedures can be improved by using surface markers glued to the patient's skin. In this case their location can be more precisely determined using the pointer, and they can be automatically identified within the patient's three-dimensional images. While this improves the precision of the matching, there remains the problem that skin mounted markers can move with respect to the underlying bony anatomy, and therefore add additional error. Maurer *et al.*¹⁰ have demonstrated convincingly that the only way to achieve patient-to-image registration with the same accuracy as can be obtained with a stereotactic frame is by using bone-mounted fiducial markers. Even though the implantation of these reference markers constitutes a procedure that is approximately as invasive as the installation of a stereotactic frame, it can nevertheless be performed under local anesthetic and represents a level of invasiveness that is minor compared to the surgical procedure that is to follow. Maurer *et al.*¹⁰ show that the accuracy and precision obtainable with properly designed markers is in the order of 0.5 to 1.5mm.

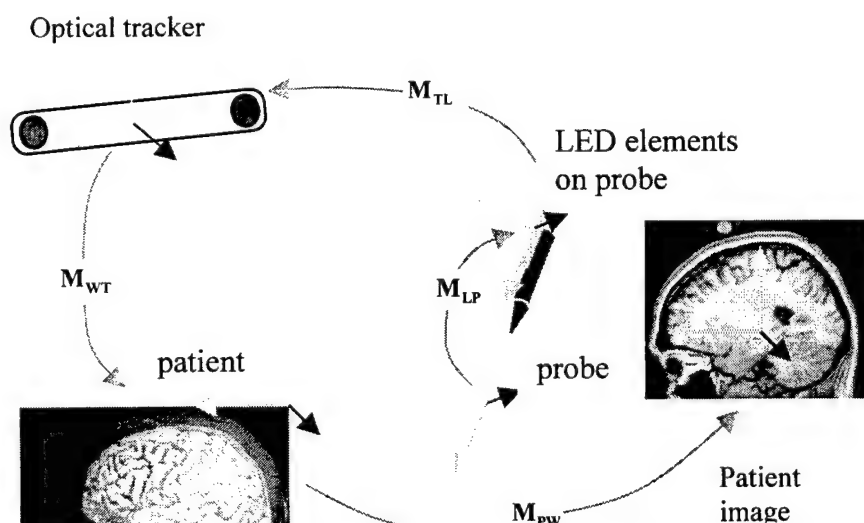


Figure 2. Typical instrument tracking scenario. The symbols M_{xx} represent the transformation matrices relating various coordinate systems. The transformation matrix describing the relationship between the probe and the patient image is a concatenation of these transformation matrices.

2.6 Tracking Systems

Tracked probes provide the key to image-guided surgery. Mechanical,^{9,11} ultrasonic, magnetic,¹² or optical¹³ methods have all been employed to determine the probe's position, but the use of optical trackers (both active and passive) has now become almost universal. Until recently there was no satisfactory means of tracking an object (for example a catheter tip or a flexible endoscope) within the body unless one employed a real-time imaging system like MRI,¹⁴⁻¹⁶ ultrasound,¹⁷ or fluoroscopy. Recently, miniature magnetic sensors^{ab} have become

available that can be inserted in a catheter, which opens the door to tracking flexible instruments within the body. Most of the devices in routine use currently report accuracies and precisions of better than 1mm, which is generally accepted as a target performance standard for tracking devices. Whatever process is employed at the registration and instrument tracking phases of the procedure, a number of coordinate transformation calculations must be made to relate the coordinates of "image-space" to those of "patient space", as illustrated by Figure 2.

2.7 Intra-operative imaging.

Although tracking systems allow image-guided surgery to be undertaken without frames, and permit dramatic expansion in the scope of procedure to which it could be applied, the move to encompass open-craniotomy procedures brought other problems. The absence of the frame compromised the accuracy with which the images could be registered to the patient, and the fact that the tissue could move during the procedure meant that the pre-operative images did not necessarily represent the state of the tissue accurately during surgery. A great deal of effort has been spent on image-to-image and image-to-patient registration techniques, and means of combining real-time intra-operative imaging with images acquired pre-operatively. Approaches to this problem include the use of "open" MR magnets, which allow the patient to be imaged dynamically during the procedure,^{18,19} and intra-operative imaging using standard magnets that can be employed to image the patient at several time-points during the surgical procedure.²⁰ These approaches are expensive and somewhat unfriendly with respect to the OR environment. In response to this problem, the use of intra-operative ultrasound has been employed either alone,^{21,22} or in conjunction with pre-operative MRI.^{23,24}

3. MULTI-MODALITY IMAGING

Although CT was the primary imaging modality originally employed for stereotactic surgical planning, it soon became evident that it could be complemented by other imaging modalities. In particular, the combination of MRI and digital subtraction angiography provides both anatomic and vascular information; while MRI (or CT) and PET (or Spect / fMRI) provided anatomical and functional data in the same image volume. For this reason, multi-modality image display and analysis systems were developed to allow the planning and guidance operation to take place using multiple image data sets simultaneously.²⁵⁻²⁷ Many of these techniques are discussed in a recent comprehensive review on image registration.²⁸

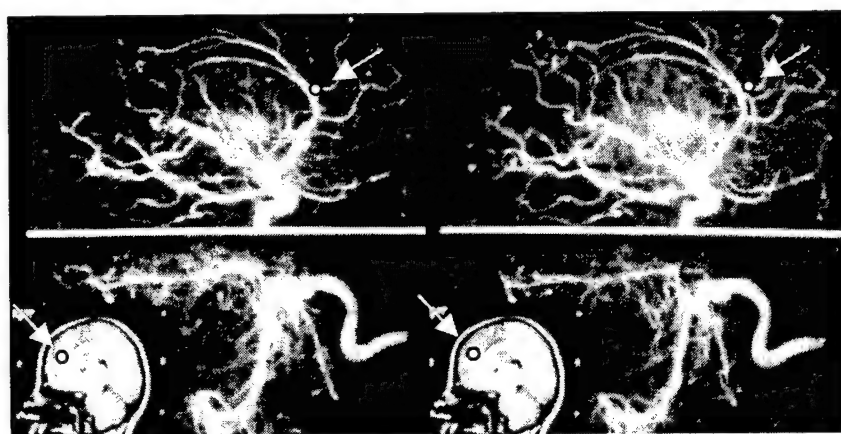


Figure 3. Stereoscopic (crossed-eye) view of lateral (top) and anterior-posterior (bottom) angiograms along with registered MR image. A 3-D cursor (arrows) driven through the volume defined by the angiograms is tracked in the appropriate slice of the MR volume.

Although MRI and CT are three-dimensional imaging systems and digital subtraction angiography is two-dimensional, it is nevertheless possible to display the projection of a point identified in the 3-D modality within the 2-D angiogram. Likewise a point within the planar angiogram can be represented as a line within the MRI or CT volume. By employing orthogonal or stereoscopic angiogram pairs, three-dimensional localization

^b <http://www.ascension-tech.com/products/minibird>

can be achieved within the angiogram-defined space (Figure 3). This multi-modality approach was particularly important when planning trajectories to deep brain structures, or when implanting EEG recording electrodes during a procedure to localize the foci of epileptic seizures.^{29,30} In both cases, it is important to ensure that the trajectory follows a path that is free from major blood vessels. This can be easily achieved by verifying the trajectory that is planned on the basis of the MRI or CT images by examining its projection within the angiogram images.

3.1 Physiology

Physiological information is often useful as a complement to the anatomical data furnished by MRI, CT or angiography. In addition to the information derived from PET or fMRI some neurosurgical procedures (such as the therapy of Parkinson's disease) rely heavily on electrophysiological information, recorded from deep-brain electrodes. Mapping the electrophysiological responses recorded during such procedures onto the 3-D anatomical images of the patient helps the surgeon navigate towards the desired target. Moreover, a database of such responses, normalized through non-linear image registration to a standard data space, can be integrated with the patient's 3-D MRI to assist the surgeon by predicting the likely target for creating a therapeutic lesion³¹ (Figure 4).

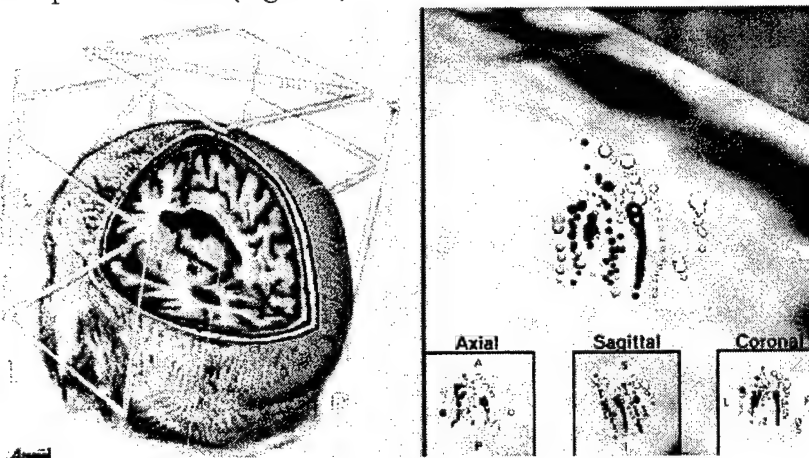


Figure 4 Atlas of Facial, Finger, and Foot paresthesias evoked by microstimulation (300Hz stimulus, $< 100\mu\text{A}$, 0.2ms) derived from 26 patients. Left: Location of stimuli coordinates within deep brain region of individual patient. Right: magnified region showing somatopy (facial responses in white, finger responses - black, foot responses - grey)

(derived from 3-D medical imaging) into the same space occupied by the physical object, through the use of half-silvered mirrors suspended above the operative site^c, or head-mounted displays.^{34,35} Using stereoscopic visualization and appropriate head-tracking, this approach can place a realistic 3-D virtual image of the organ in the same physical space occupied by the actual organ.

3.3 Microscopes

Since many surgical procedures involve the use of an operating microscope, the integration of the microscope images with those obtained from preoperative MRI and CT scans is a natural application of augmented reality. In this case the images from a tracked microscope can be integrated electronically in a digital or analog fashion, with the combined images being displayed on a video or computer monitor.

3.2 Video

Intra-surgical video images can add a great deal of information to an image guided surgical procedure. The integration of the real and modeled worlds in this manner is often referred to as augmented or enhanced reality visualization. Kikinis³² and Davey³³ demonstrated the efficacy of integrating a video image of the operative site with the graphical representation of a tumor or other target structure. In this manner, the surgeon can "see-through" the patient's skin into the operative site, to facilitate the planning of an optimal approach to the surgical target. More recently, other investigators have achieved similar results by integrating virtual images

^c <http://www.mrcas.ri.cmu.edu/projects/overlay/system.html>

Alternatively, the images from the preoperative scans can be projected into the visual field of the microscope.³⁶ This technology has also been incorporated into head-mounted displays where the position of the surgeon wearing such a display is tracked and the preoperative image corresponding to the viewpoint of the surgeon is projected on his field of view.³⁷

3.4 Endoscopes

While an operating microscope can "see" into an operating site through a skull opening greater than about 2 cm in diameter, when we seek to visualize the target directly through a smaller opening, other means must be employed. The endoscope has been used for many years to gain visual access to body cavities, and has

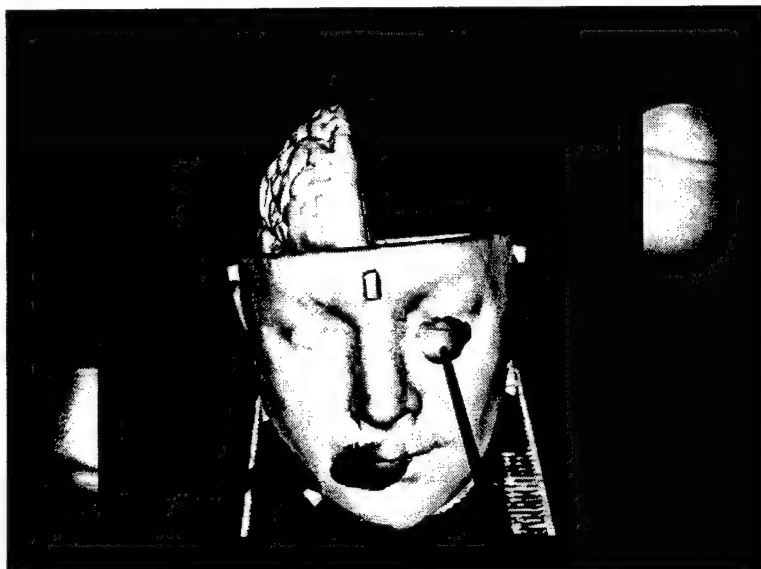


Figure 5. Endoscopic images from a tracked endoscope, mapped onto the surface defined by a 3-D digital model of the original object.

been employed in neurosurgery to assist in surgical procedures within the ventricles. A technique that has become popular recently is "virtual- endoscopy,"^{38,39} which uses computer graphics to simulate the view of an endoscope placed in a particular body cavity, based on the representation of the cavity derived from preoperative MRI or CT images. With the increasing emphasis on minimally invasive surgery, there has recently been an active interest in combining the video images from standard endoscopy with the computer-generated images of virtual endoscopy. The aim here is to place the endoscope image observed during a minimally invasive surgical procedures, in its proper context by merging it with the equivalent surface extracted from the preoperative images. Several authors have recently reported on the clinical application of combining images of the ventricle wall

obtained from a tracked endoscope, with the equivalent images from CT or MRI.⁴⁰⁻⁴² The simplest mode of operation of this approach is to simply track the tip of the endoscope, and display the tracked point on orthogonal image slices derived from the original data. The most convenient means of achieving this goal is to display the three slices that intersect at the tracked point. However, in order to place the endoscopic image in its proper context, a surface rendition of the cavity within which the endoscope resides is constructed, onto which the video image produced by the endoscope may be mapped. Figure 5 is an example of an endoscopic image after proper rectification to remove lens-induced distortions, as well as those due to the arbitrary shape of the organ surface, that has been accurately mapped onto the surface of the image derived from a 3-D CT volume.

4. NON NEUROLOGICAL APPLICATIONS

4.1 Orthopedics

Computerized image-guidance of spinal and orthopedic procedures has lagged somewhat behind its application in neurosurgery, but it is rapidly growing in popularity. Lavalée *et al.*⁴³ discuss a computer-assisted surgical system for navigation during spinal surgery, using CT images as guidance. Their approach follows closely that outlined for IGNS. This same group⁴⁴ describes a similar technique for anterior cruciate

ligament reconstruction. This system uses a workstation and a three-dimensional optical localizer to display images that recreate knee kinematics. In the future, it is expected that standard arthroscopy will be combined with a tracking system and "virtual arthroscopy" based on high quality MR and/or CT images of the joint to assist in such procedures.

Foley *et al.*⁴⁵ point out the limitations of 2-D conventional imaging techniques for spinal navigation, and describe a three-dimensional image-space representation of the surgical volume, using a specially designed referencing system and computer workstation, while Nolte⁴⁶ discusses the use of interactive navigation of surgical instruments for the fixation of spinal implants. The use of rapid 3-D MRI was investigated by Martel *et al.*⁴⁷ to acquire images suitable for image guided surgery of the spine. They employ a very fast 3-D MRI sequence, with a wide bandwidth and short echo time (TE) to minimize susceptibility distortions, along with MRI/CT compatible fiducial landmarks. This permits the validation of the MR approach against CT, and demonstrates that the registration can be undertaken with an accuracy of 0.4 mm using 3-D MRI. They show that MR can effectively be as accurate as CT for spinal imaging in this context, and conclude that MRI shows promise for use in computer assisted surgery of the spine.

4.2 Breast

Using the GE intra-operative magnet discussed above, Gould *et al.*⁴⁸ demonstrated that interventional MRI is an effective tool for accurately identifying palpable breast tumors and guiding their surgical excision. The use of radiographic and ultrasonic techniques for image-guided breast surgery is increasing, but is currently restricted to fine needle aspiration and core biopsy, as discussed by Staren *et al.*^{49,50} They comment that future care of patients with diseases of the breast will continue to be increasingly dependent on image-guided breast biopsy techniques. This approach should avoid many unnecessary open biopsies for benign lesions and facilitate therapeutic planning for malignant lesions. The increasing use of computer assisted stereotactic radiographic and ultrasound breast imaging is also reviewed by Burns,⁵¹ who suggests that such techniques to guide percutaneous core sampling of the abnormal area are less invasive, less painful, highly accurate, and less expensive than incisional breast biopsy with preoperative needle localization.

4.3 Prostate

Image guidance is common in treatment of prostate cancer, but its application is focused on therapy (via cryosurgery or brachytherapy) rather than surgical removal. The most common modality in use for image-guided therapy of the prostate is ultrasound, and the recent development of 3-D trans-rectal ultrasound (TRUS) imaging techniques⁵²⁻⁵⁴ has had a positive impact on this field. When employing 3-D TRUS for therapy, a series of 2-D US images, uniformly spaced in angle, are reconstructed to form a 3-D volume. This is registered with a therapeutic probe (radio-active seed implant device or cryosurgery probe) and manipulated in much the same manner as a lesioning device is introduced into the brain. Intraoperative 3-D TRUS provides unique, pseudo real-time views of the prostate, which facilitates the optimal placement of the probes.

4.4 Heart

As in other regions of the body, minimally invasive surgery techniques have begun to play an increasing role in cardiac surgery in an attempt to reduce the significant trauma and long recovery time associated with traditional coronary bypass surgery. Conventional coronary bypass surgery requires a sternotomy and a cardiopulmonary bypass procedure that subjects patients to significant trauma and lengthy hospital stays. Over the past few years, minimally invasive direct coronary artery bypass (MIDCAB) procedures have been introduced, performed via instruments introduced into the chest via trochars and guided endoscopically. Such techniques are making a significant impact on cardiac surgery, but because of the extreme difficulty in manipulating the instruments at the distal ends of the trochars, several groups have recently begun to

perform coronary bypass surgery on the beating heart in the intact chest using tele-operated robots inserted into the chest via intercostal ports.⁵⁵⁻⁵⁷ The use of robots increases dexterity and reduces the effect of tremor in the surgeon's hands.

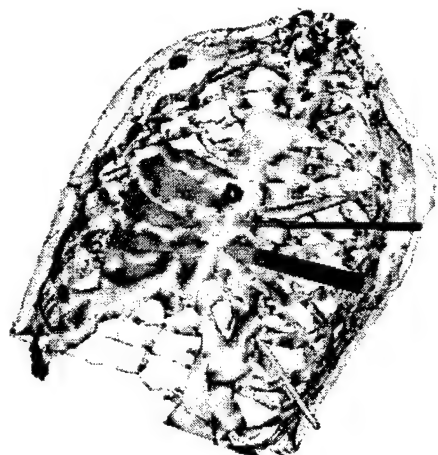


Figure 6. Simulated environment for robotically-assisted coronary bypass surgery, showing positions of robotically-controlled surgical ports endoscope.

In spite of the sophistication of these robotically assisted systems, the use of images in the planning of the procedure is presently limited to conventional chest-radiographs and angiograms. The use of such simple images makes it extremely difficult to plan the positions for the entry ports between the ribs, and does not allow for any level of guidance during the procedure. The operation must be carried out solely under the guidance of a 1-2 cm diameter field-of-view delivered by the inserted endoscope. Several laboratories have recently extended the expertise developed in neurosurgical guidance to build a virtual cardiac surgery environment, which combines 3-D CT and 4-D (dynamic) MRI to present the surgeon with a model for planning and guidance during the procedure^{58,66} (Figure 6). Initially, these efforts have been based on static cardiac images aimed at planning appropriate inter-costal port locations and robot orientations. This work is however moving rapidly in the direction of virtual dynamic surgical simulation, planning and guidance environments, that will synchronize the

dynamics of the modeled cardiac environment with that of the beating heart.

5. COORDINATED APPLICATION DEVELOPMENT

Many groups across the globe are working on problems in image-guided surgery, and many different software and hardware platforms have been employed. This situation not only makes it difficult to share resources across the community, it also raises the problem of legacy software being constrained to a particular (outdated) hardware platform. Nevertheless, over the past few years, many groups have begun to use the rapidly evolving VTK^h environment for developing medical imaging applications. Working with such a suite of robust tools has significant advantages producing increased development speed, reliability, and reusability of code. In addition, its open source nature encourages contribution from the user community. The development of new applications in medical image visualization and surgical planning requires the completion of many common tasks such as reading, re-sampling and segmenting images, followed by visualization via surface or volume rendering, etc. The intra-operative use of such tools requires that images be registered to the patient, and that tools and probes are tracked. For such systems to be employed by someone other than the original author, the user must be provided with basic, easy to understand user interface components. Computer and end-application hardware changes rapidly, as do operating systems and network environments. Such factors emphasize the advantages of having access to an independent collection of reusable software components that are hardware and operating system independent, and which can be assembled rapidly to prototype new applications.

^h <http://www.kitware.com>

In our lab, we have developed a set of such components that address some of the above-mentioned concerns.⁵⁹ They are written in both C++ (some as VTK classes) and Python, but all are accessible from Python, a byte compiled scripting language that is gaining rapid acceptance. Applications built using these components have been used on the Red Hat Linux, Silicon Graphics Irix, Microsoft Windows, and Mac OS X platforms. Rigorous object oriented software design methods have been applied to ensure hardware independence and a standard application programming interface (API). There are components to acquire, display and register images from MRI, MRA, CT, Computed Rotational Angiography (CRA), Digital Subtraction Angiography (DSA), 2D and 3D ultrasound, video and physiological recordings. We have also implemented interfaces to various tracking systems for intra-operative use. Over the past two years, these components have been used to create general image manipulation and viewing tools, a deep brain functional atlas³¹ (Figure 5), a 3D ultrasound acquisition and display platform²⁴, a tracked neuroendoscope guidance system⁶¹ (Figure 6), a prototype minimally invasive robotic coronary artery bypass graft planning system⁵⁸ (Figure 7), and a frame-based stereotaxy neurosurgery planning tool⁵⁹. We believe that by following this approach, new applications can be developed more rapidly, they can be readily tailored towards the needs of users, and the transition from a research to a clinical/commercial environment can be facilitated. Further details of this approach can be found in Starreveld *et al.*⁵⁹

6. CHALLENGES IN IMAGE-GUIDED SURGERY

The current emphasis on the use of minimally invasive therapies in all parts of the body has made image-guidance for therapy and surgery a rich area for research and development. Many of these applications present fascinating problems, and one of the most challenging is in the area of minimally invasive robotically-assisted cardiac surgery, where therapy is performed on the beating heart through several small holes between the ribs. In order to adequately provide full intra-operative image-guidance to the surgeon during the procedure, not only must pre-operative dynamic images be matched to the intra-operative anatomy of the patient but proper account must be taken of the complex relative motion undergone by the heart and thorax during the procedure. Currently, the efficacy of this procedure is limited by the lack of sophistication of the robotic end-effectors, allowing only single accessible coronary vessels to be bypassed using this procedure. Improvements to the dexterity of these robots will enable more complex procedures to be performed using these minimally-invasive approaches.

Factors currently limiting the wide acceptance of image-guided surgery include the lack of universal image standards, less than intuitive user interfaces, differences in image-registration protocols, incompatibility of surgical tools with guidance systems, lack of adaptation of systems to user preferences, and inherent errors in imaging and tracking systems. While it is true that the introduction of ACR-NEMA followed by DICOM-3 has gone a long way towards the creation of a universal image format standard, there nevertheless remain many DICOM "flavors". In addition, DICOM does not directly support 3 and 4-dimensional datasets or 3-D objects. Images are still treated as a series of "byte-slices" rather than as samples of some parameter within a multi-dimensional space. Some of these limitations have been addressed by the MINC (Medical Image Net-CDF) format, based on Net-CDF and extended at the Montreal Neurological Institute by Neelin *et al.*^{60d} MINC adopted by many groups in the neuroscience imaging community and beyond as an effective format/environment for medical imaging research. The need to evolve coherent user interface and interconnectivity standards that could be adopted by multiple manufacturers was expressed by Bucholz in his recent keynote address at the MICCAI-2000 meeting. To this end he has proposed the SurgON standard^e,

^d The MINC Format. MNI Website. <http://www.bic.mni.mcgill.ca/software/minc/minc.html>

^e <http://Thalamus.slu.edu/SurgON/>

that, if adopted universally, could solve many of the inter-connectivity and user interface problems that exist with current systems.

7. SIMULATION

The development of tools for image-guided surgery and therapy has led to the need for an environment to accurately represent the patient using computer methods, to simulate surgical and therapeutic procedures in as realistic a manner as possible, without involving human subjects. This approach becomes particularly important as surgical procedures become minimally invasive and robotically assisted. The need for accurate simulation in this environment can be likened to the need for simulation in the aviation industry, i.e. exposing the pilot/surgeon to realistic scenarios and monitoring their responses.

Simulation fulfills the needs to compare alternative procedures, develop and refine interventions, reduce complications, increase predictability, train practitioners, customize instruments and devices, and improve outcomes. The input data for such a simulator are acquired from multiple imaging modalities, including CT, ultrasound, and MRI, and can be in the form of pre-, intra- and post-operative three-dimensional images. In reality, simulation is part of the continuous spectrum that already exists for image-guided surgery. The level of realism in the presentation of the data allows us to progress from simple guidance of the procedure to realistic simulation. Models of the skeleton and soft tissue may now be synthesized from volumetric images, and visualized and modified interactively. Individualized electronic regional body atlases may also be created using deformable templates or by applying image fusion/registration methods. Once modeled and visualized, simulation is accomplished with various interactive devices, both visual and tactile, that mimic biopsy, minimally invasive, and open surgical and therapeutic procedures, tele-surgery, intraoperative navigation, virtual endoscopy, gene therapy, and can provide the necessary training. Glombitza *et al.*⁶² recently presented an overview of the state of the art of virtual surgery, citing its use in a variety of environments.

An important aspect of realistic simulation is the force feedback sensed by the operator conveying realism at the tactile level. This probably represents the most difficult aspect of the simulation cycle. While sophisticated multi-degree of freedom force-feedback (haptic) devices exist (Sensable Technologies Inc^f, MPB Technologies^g), they are limited to applying linear or rotational force feedback to the operator, are not able to provide textural information (to the fingertips for example), and may be limited with respect to the rate at which they can respond to input. It is likely that in some instances, physical models (registered spatially with the virtual model) could be employed to provide the appropriate haptic feedback when performing such procedures as cutting and probing tissues. An example might be an Agar or Poly-vinyl alcohol cryogel⁶³ phantom that has been manufactured to simulate the mechanical properties of the tissue being modeled. If the underlying finite element model that is driving the mechanical simulation and visualization is sufficiently sophisticated to mimic the behavior of the phantom (when cut for example), the physical model could provide much of the necessary mechanical feedback to the operator.

8. FUTURE DIRECTIONS

Although image-guided procedures are commonplace in neurosurgery, there have been few efforts to quantify their effectiveness, either in terms of patient outcome or cost savings. One study that has attempted to do so was presented recently by Paleologos *et al.*,⁶⁴ who demonstrate some benefit (in terms

^f <http://www.sensable.com/products/6dof.htm>

^g http://www.mpb-technologies.ca/space/p_freedom6s.html

of reduced complication rates, shorter hospital stays) through the use of image-guidance for meningioma surgery via craniotomy vs. conventional approaches. They point out that it is difficult to construct robust studies to validate such procedures, and that many of the advantages relate to the increased comfort of the surgeon performing the procedure. While difficult to generalize from this small study, they acknowledge the additional benefits of integrating multi-modality imaging and correcting for intra-operative brain shift would be expected to significantly enhance the acceptance of such techniques. While image-guide surgery systems are becoming increasingly sophisticated perhaps the greatest challenge to the successful adoption of image-guided surgery systems in the operating room of the future, relates not to the technology, but to the user interface and the acceptance of the technique. Over the last few years, inexpensive high-speed computing hardware has become available to allow interactive surgical image-guidance to be performed in real time, with the images presented to the surgeon in a "virtual-reality" format. However, little effort has been expended to date on ensuring that the human factors issues relating to the use of such equipment in the OR have been adequately addressed. Visarius *et al.*⁶⁵ point out that the majority of image-guided surgical systems in clinical use still require the involvement of a "systems engineer" to ensure that the procedure runs smoothly. It is incumbent on all who develop such systems that they focus on reducing the cost of the equipment, making it available on demand, and designing it so that it can be used by OR staff as a routine item of surgical equipment. Patient images must be automatically available in the OR in the appropriate format; patient-image registration steps must be trivial and robust, all tools should be recognized and trackable by the system, and images need to be integrated with the actual patient view so that the surgeon is not constantly changing his visual field. It will only be when such systems are unobtrusive, provide simple access to the image sources and can be operated in an intuitive manner by traditional operating room staff, that they will be employed routinely in the OR.

Beyond neurosurgery, minimally-invasive image-guided techniques will continue to play increasingly important roles in cardiac surgery, breast, orthopedic surgery, prostate therapy, and brachytherapy of various organs. The use of tele-robotic control will increase the precision of these procedures through tremor control and dexterity enhancement, and permit more procedures to be performed under direct image guidance (in conventional MR scanners or high dose-rate x-ray fluoroscopy). In addition, many of the techniques discussed here are finding application in conventional external beam radiation therapy.

9. CONCLUSION

Image-guided approaches have evolved significantly over the past 20 years and stand to make further important contributions to a variety of surgical and therapeutic procedures, rendering them less invasive and less traumatic to the patient. There are many challenges in the path of the general acceptance of these techniques by the surgical community. In addition to the general lack of quantifiable evidence regarding the demonstrable efficacy of these approaches, there is a natural reluctance of many practitioners to embrace technology-based approaches, particularly when faced with the prospect of having to learn on a new paradigm, or to place reliance on an additional level of "engineering" support during the surgical procedure. For this reason, the key developments in this field must include the provision of a largely automated and "bullet-proof" infrastructure, where image-management becomes a trivial operation, the delivery of user interfaces that are intuitive and non-threatening and the ability to make systems available to the surgeon on demand with a minimum of additional planning.

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Outline of Surgical Simulation

Kevin Cleary and Robert L. Galloway Jr.

Medical Simulators are interactive virtual environments used to improve human performance of medical tasks. While they need not be computer-based the focus for this paper is personal computer-based systems. The uses of surgical simulators are many. First is medical education and or training. The population here can range from experienced physicians learning new procedures to nurses, medical students, military medical corpsmen, emergency medical personnel and even to the general public for first aid procedures. Simulators can also be used for scientific analyses such as biomechanical studies or device design and testing. With the advent of the image-guided procedures described elsewhere in this document, it should be apparent that simulators could allow for more realistic preprocedural treatment planning.

Types of Medical Simulators

There are several types of surgical simulators. The list includes: plastic mannequins, computer based mannequins and virtual environment simulators. While each has their own uses there is a growing convergence of system. However, for simplicity's sake they can be grouped as below:
Plastic mannequins - Physical models for practicing procedures such as intubation and IV placement. Examples are the patient simulators MedSim and METI. They have computerized sounds and physiology and are used for skill assessment and trauma training applications.

An example of a plastic mannequin is shown in Figure 1.

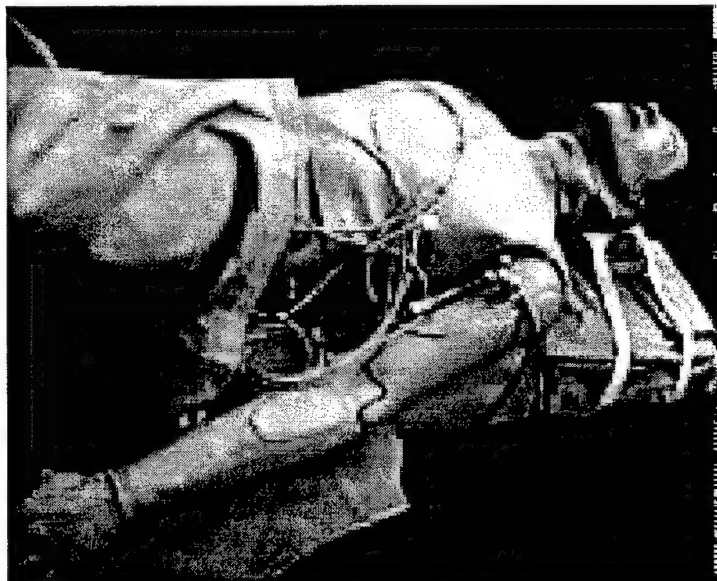
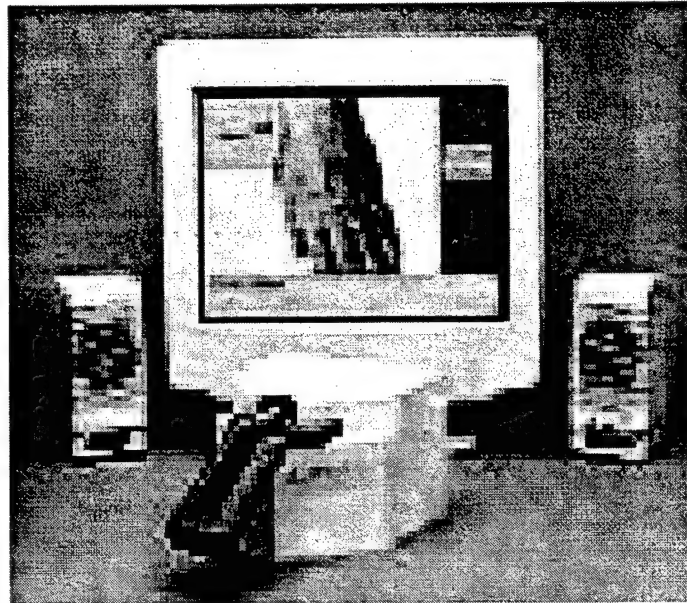


Figure 1.

The second class of medical simulators are computer-based mannequins. These simulators are used for training and testing skills in anesthesiology and related applications. The information is provided by visual feedback on a computer system of anatomic structures and physiologic signals corresponding to the users input parameters. An example of a computer based mannequin is shown in Figure 2.

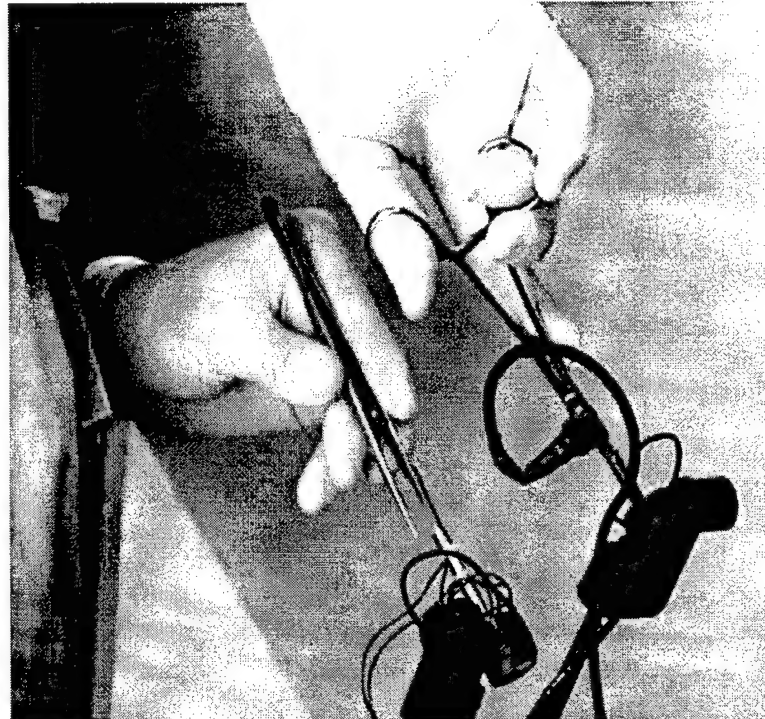
An example of a computer-based mannequin is the CathSim Needle Insertion Simulator from Immersion Medical. Here a tactile interface with a physics-based simulation is provided. The role of this simulator is to provide assessment of skills in patient case studies. By having such a controlled environment, studies can be performed across groups of users and longitudinally in users to measure changes in skills.

Figure 2



The final major class of medical simulators are Virtual environment (VE) simulators - Contain a computer graphics model and provide an immersive experience. One example of this class on simulator is the Virtual Surgery Simulator from Boston Dynamics, Inc. (shown in Figure 3). Here a Mirror-based workbench and Stereoscopic glasses place the image in the physicians natural visual field. Feedback is provided both with the haptic PHANToM interface and audio information.

Figure 3



Example of Medical Simulation System

A joint effort between Georgetown University and the Korean Advanced Institute of Science and Technology (KAIST) has been developing a spine biopsy simulator. Here their concern is for a common medical procedure which has a well described physiological structure. The relatively simple anatomy and interventional nature of the procedure make this application well-suited to simulation.

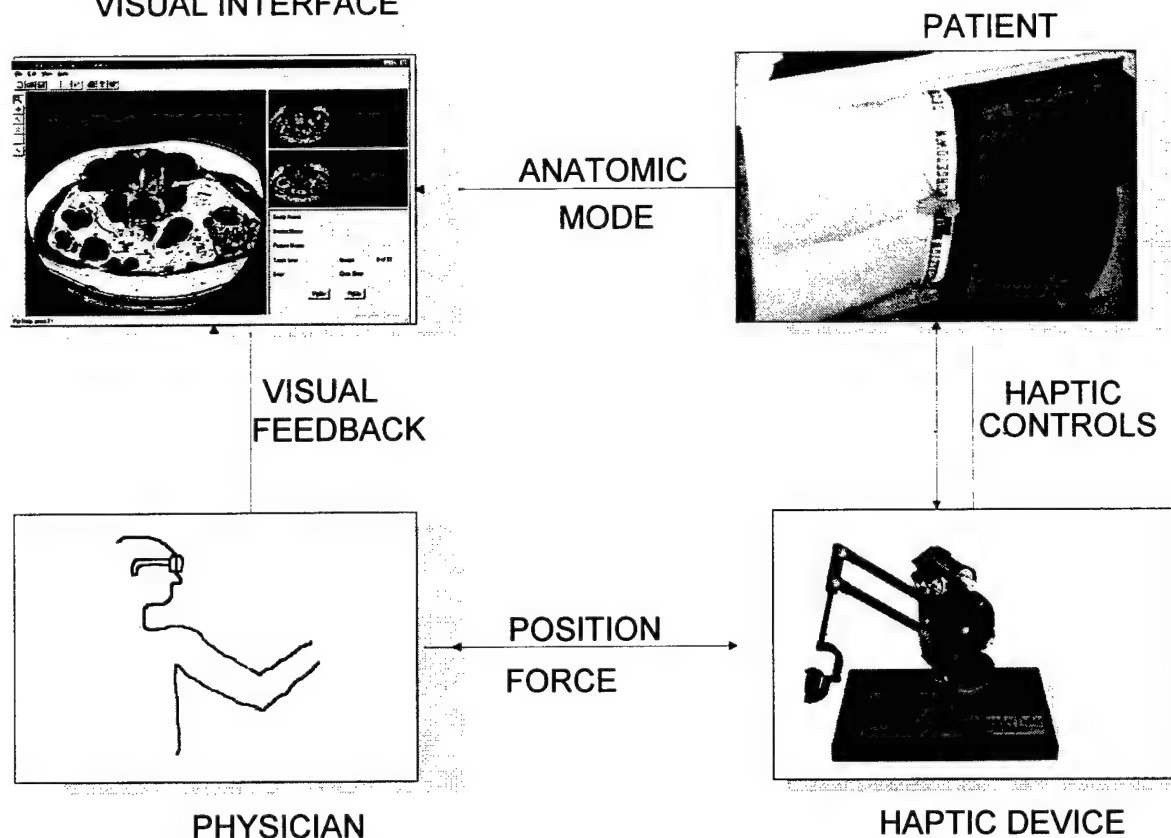
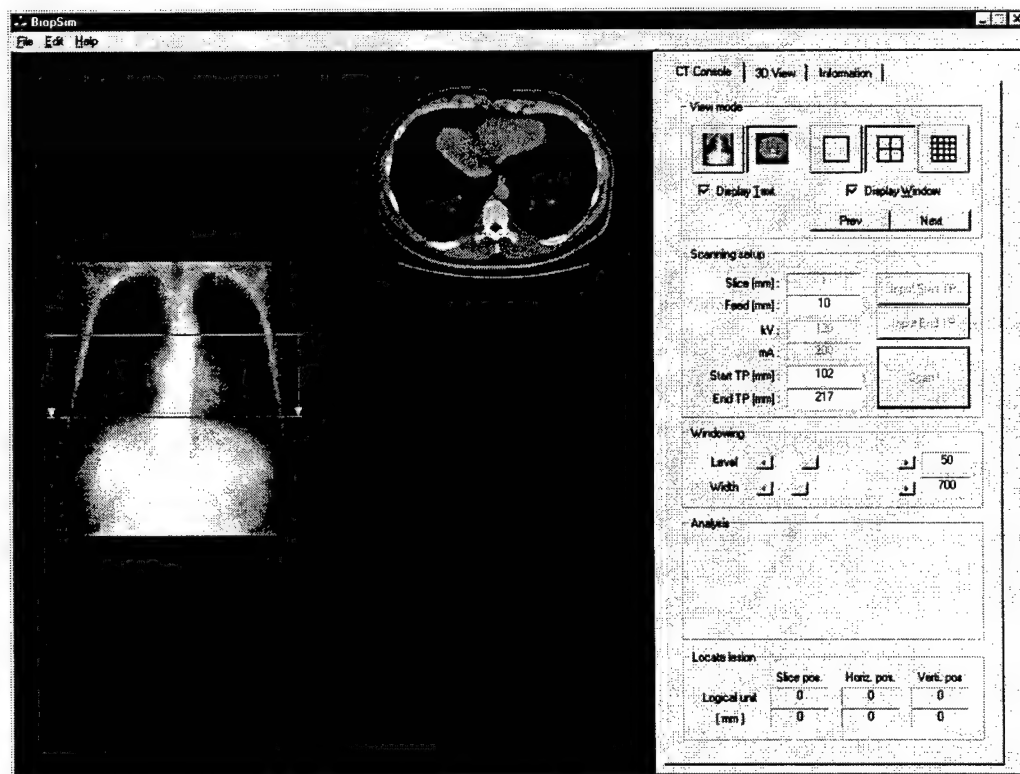


Figure 4

The Spine Biopsy simulator is shown in the diagram in Figure 4. Individual components of that device include the user interface shown in Figure 5.

Figure 5

GUI developed by the Image Systems Lab, Dept of Electrical Engineering, KAIST, Korea, Directed by Dr. Jong Beom Ra



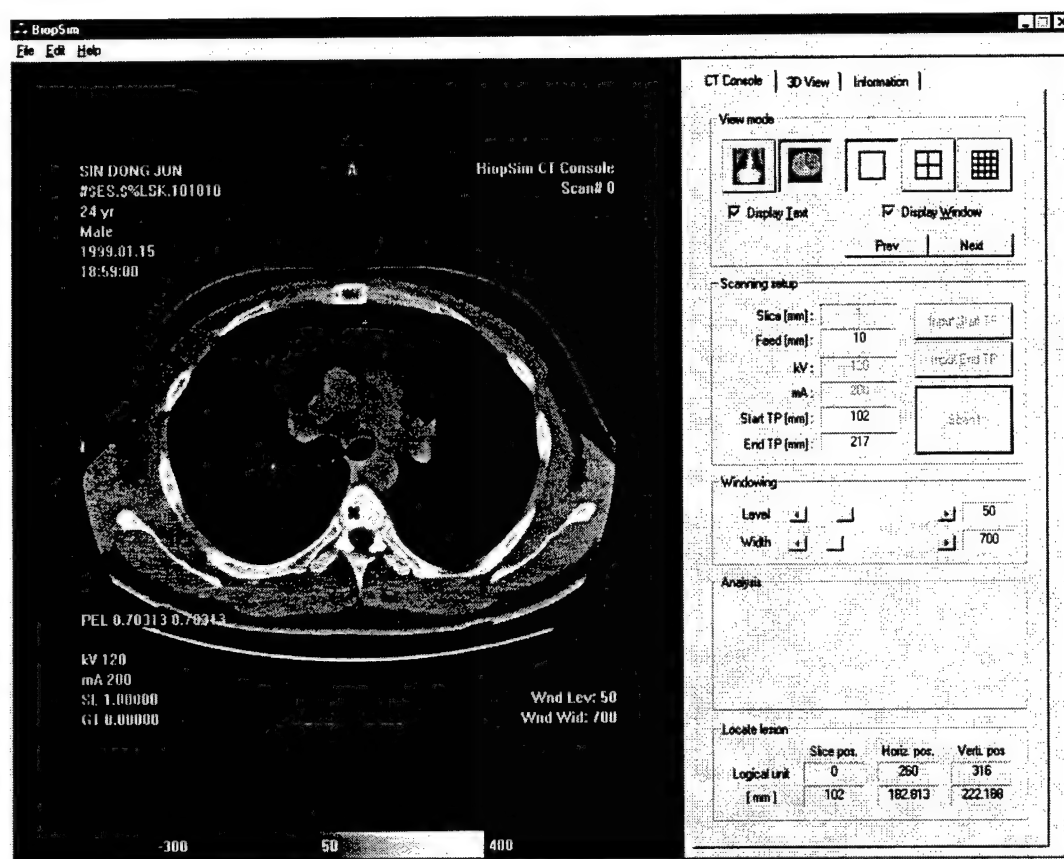
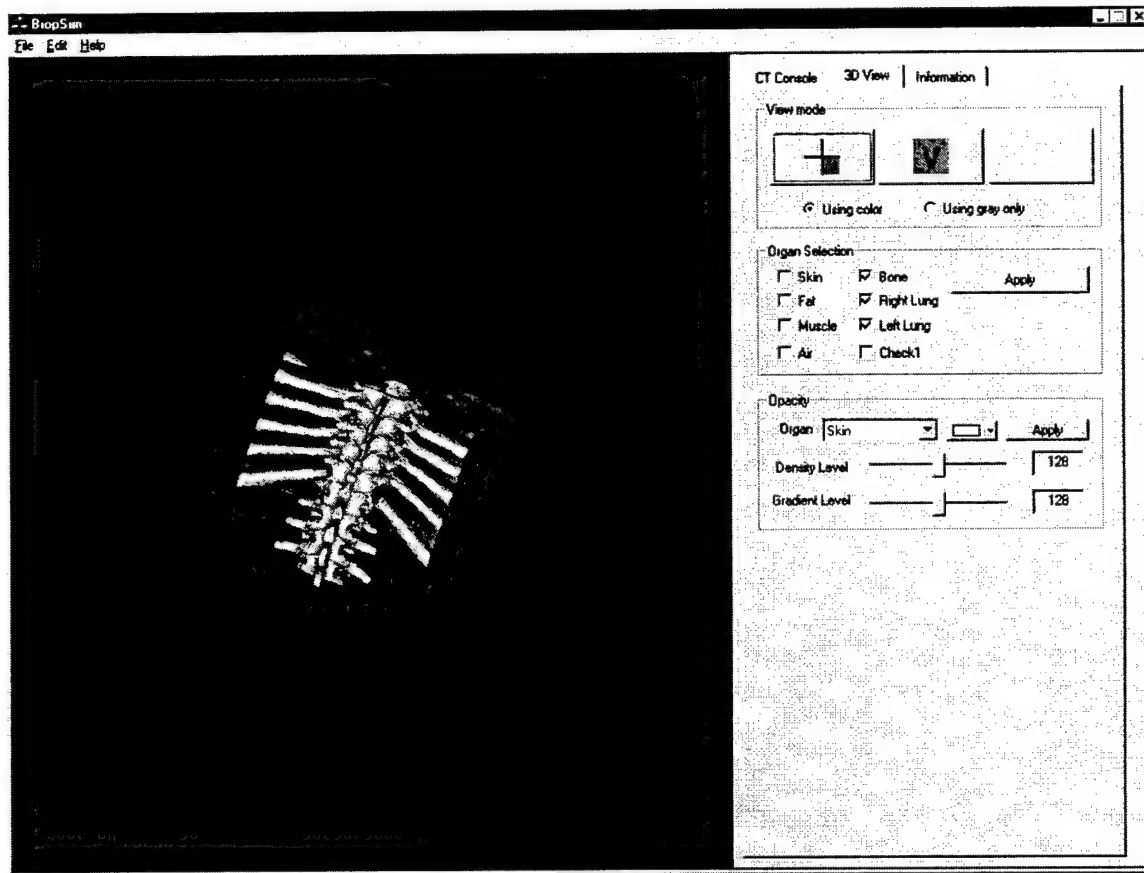


Figure 6.

As shown in Figure 6 the GUI can provide axial views of the simulator's "progress" into the tissue as well as three-dimensional renderings such as the one shown in Figure 7. Since the screen is two dimensional and the task is three dimensional, multiple image types are needed to provide the desired guidance.

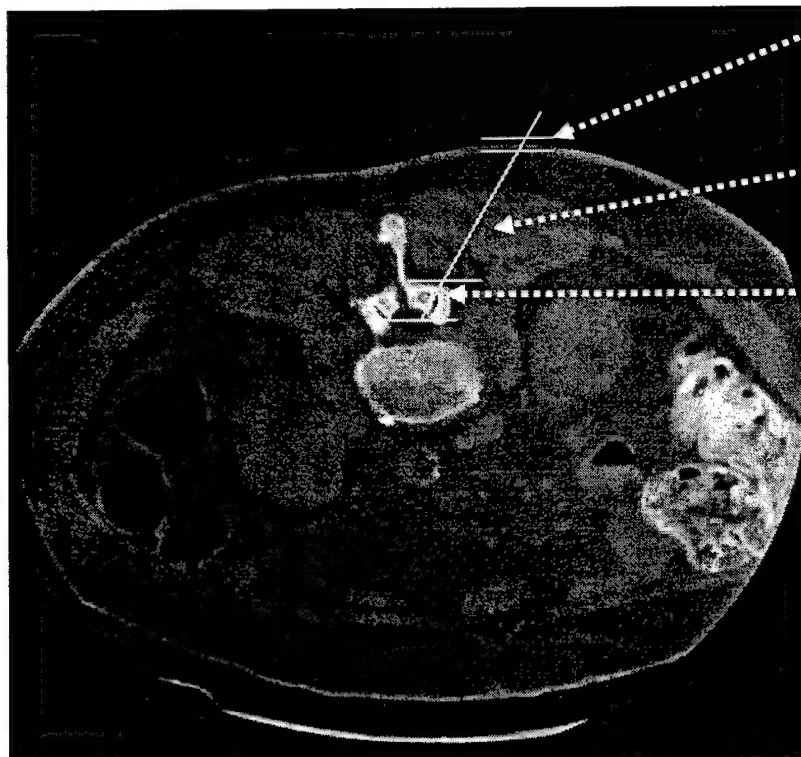


Beyond the matching of physical and image position, the goal of a simulator is to provide a “feel” to the user. Therefore it is desirable to provide accurate real-time replication of interaction between an instrument & soft tissue. For the spinal procedures there are classes of anatomical models: non-deformable, deformable surface-based and deformable volume-based. The force-feedback methods include a tissue/force profile scheme, surface rendered modeling and finite element analysis.

For the spine procedures a heuristic model consisting of 3 regions was developed.:

1. Initial needle puncture (fat to muscle)
2. Homogeneous force (muscle)
3. Hard stop (bony structure)

These zones are shown in Figure 8.



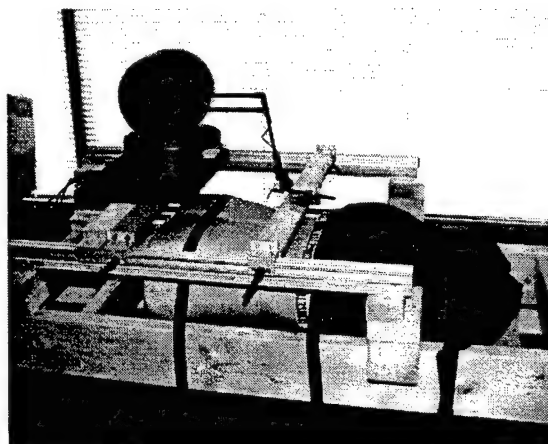
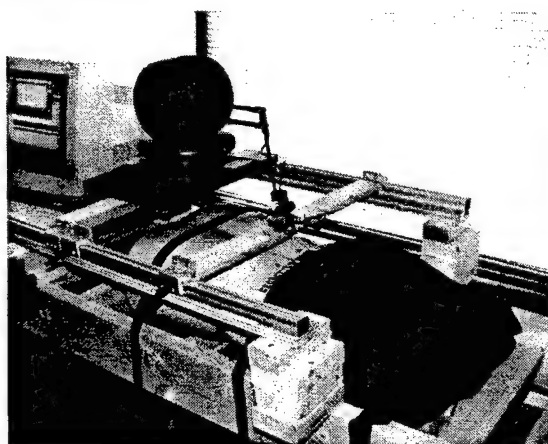
Fat

Muscle

Bone

Figure 8.

The physical interface for the simulator is shown in figure 9. In this device the position of the probe is tracked and force feedback appropriate to the zone of application is provided by the PHANTOM haptic device.



Spine
Biopsy
Simula
tor
Model

Figure 9

In Figure 10 a close-up of the interface is shown.

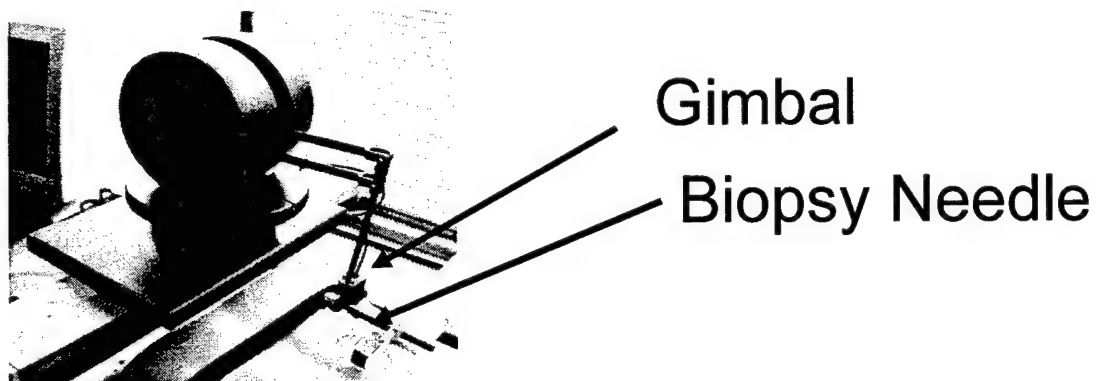


Figure 10

Conclusions

Surgical or procedural simulators can provide standardized training for specific procedures. They are flexible, allowing reprogramming to represent a variety of clinical presentations. While not yet ready to replace cadaveric training for all procedures, simulators can be an important adjunct with applications growing with the sophistication of the simulators.

CT-Directed Robotic Biopsy Testbed: Motivation and Concept

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ABSTRACT

As a demonstration platform, we are developing a robotic biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and an optical localizer. This testbed will be used to compare robotically assisted biopsy to the current manual technique, and allow us to investigate software architectures for integrating multiple medical devices. This is a collaboration between engineers and physicians from three universities and a commercial vendor. In this paper we describe the CT-directed biopsy technique, review some other biopsy systems including passive and semi-autonomous devices, describe our testbed components, and present our software architecture. This testbed is a first step in developing the image-guided, robotically assisted, physician directed, biopsy systems of the future.

Keywords: biopsy, medical robotics, software architecture

1. INTRODUCTION AND OVERALL CONCEPT

Biopsy is a common procedure in the medical field. While in most cases this procedure can be completed without difficulty, there are limitations to the accuracy obtainable using freehand techniques. In addition, CT-directed biopsy can be tedious and time consuming, since frequent re-imaging may be required.

For these reasons, we are developing a robotic biopsy testbed incorporating a mobile CT scanner, a small "needle driver" robot, and an optical localizer. A system diagram is shown in Figure 1

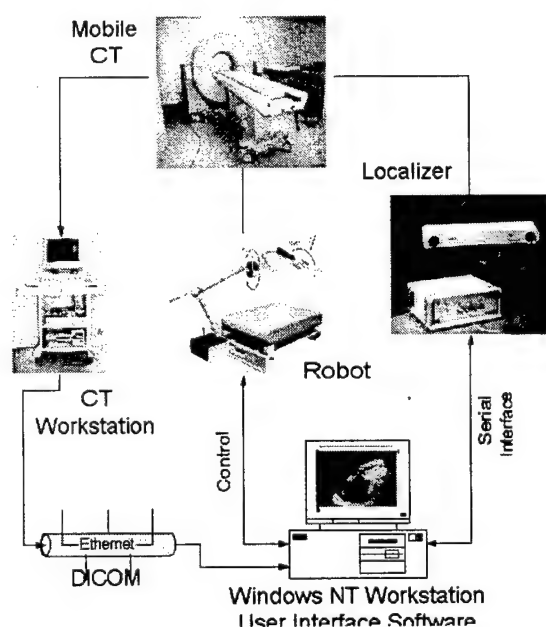


Figure 1. Testbed components

The goals of the testbed are to:

1. Develop a demonstration system for robotically assisted biopsy
2. Compare robotically assisted biopsy to the current manual technique
3. Serve as a testbed for investigating software architectures for incorporating multiple medical devices

This testbed is part of a collaboration between Georgetown and the Urology Robotics Laboratory (URobotics Lab) of the Johns Hopkins Medical Institutions (<http://urology.jhu.edu/urobotics/>) and the Computer Integrated Surgical Systems and Technology Center (<http://cisstweb.cs.jhu.edu/web/>) centered at the Johns Hopkins University. As part of this collaboration, we are also planning to apply the needle driver robot to percutaneous spine procedures such as nerve and facet blocks [1].

The remainder of the paper is organized as follows. The biopsy task is described in Section 2. In Section 3, related devices for mechanically guided biopsy are reviewed. The system components for our testbed are described in Section 4. The software design is presented in Section 5.

2. BIOPSY PROCEDURE

This procedure requires a computed tomography (CT) scanner and trained technologist; a special biopsy needle; and a "biopsy tray" with appropriate syringes, needles, anesthetic solution, and sterile towels [2, 3]. It should not be performed (unless absolutely necessary) on patients with bleeding disorders or otherwise at high risk for hemorrhage.

Each patient receives a pre-procedure CT scan to ascertain the lesion site, and to determine the safest route of approach to the lesion. Once the target and the skin entry point are chosen, the skin site is marked with a radiopaque label (such as a BB or a small needle taped to the skin). An additional axial CT image of this site is then obtained to confirm the coordinates, and calculate the desired distance from skin to target. The chosen trajectory should avoid (if possible) approaching pleura, peritoneum, or major vessels or nerves.

The entry site is then prepped with a sterile skin cleaning agent (such as povidone iodine solution), and draped with sterile towels. Local anesthetic (lidocaine HCl 1% and/or bupivacaine HCl 0.25-0.5%) is infiltrated into the entry site using a 5 or 10 cc syringe with a 25- or 30-gauge needle. After initial superficial anesthesia is achieved, the anesthetic solution may be injected deeper along the proposed biopsy track using a longer, slightly wider needle (such as a 16- to 22- gauge spinal needle). In spine biopsy procedures, care is taken to anesthetize down to and including the periosteum.

At this point, a spinal needle is inserted partially along the biopsy track, and a CT image is taken to confirm proper site and trajectory. If unsatisfactory, the spinal needle is repositioned, and additional images obtained. If adequate, the needle is advanced the rest of the way, and target acquisition is confirmed with another CT image. If the patient reports radicular pain during the needle placement, the needle is redirected; if further attempts also elicit pain, a new entry site, trajectory, and/or target may need to be selected.

Once a satisfactory angle of approach is confirmed, the spinal needle is removed, and the larger biopsy needle is carefully inserted along the same tissue path. A final CT image is obtained to confirm that the needle tip is in the target tissue before any samples are taken. Pressure is applied to the biopsy needle, along with a twisting or cutting motion (depending on the type of biopsy needle used; the recommended technique is described in the manufacturer's instructions). Before the core of tissue is removed, another CT slice is taken.

While one tissue core may suffice, many investigators take two or three samples to help ensure an adequate yield. Some may choose to have a surgical pathologist or cytologist on hand to examine the tissue specimen for suitability.

Once enough tissue has been obtained, some investigators obtain one last CT image following needle removal to demonstrate the biopsy defect in the target tissue. Direct pressure may be held on the skin entry site for several minutes to aid hemostasis, if needed.

3. LITERATURE REVIEW: MECHANICALLY GUIDED BIOPSY

Other researchers have developed robotic systems to aid in biopsy tasks. These include passive positioning systems, which provide image guidance to assist the physician in orienting the biopsy, as well as semi-autonomous robots which position, drive, and guide the biopsy needle under remote physician control. The PinPoint™ system, developed by Marconi Medical Systems (Cleveland, OH, formerly Picker), is representative of the passive robotic biopsy assistant type [4]. PinPoint is a frameless stereotactic arm for use in planning CT-guided biopsy (Figure 2a). The arm is direction encoded so that the intervention path can be visualized on CT and evaluated. Once the optimum biopsy needle path is determined, the Pinpoint arm can be locked into place to serve as a stationary guide to needle placement (Figure 2b).

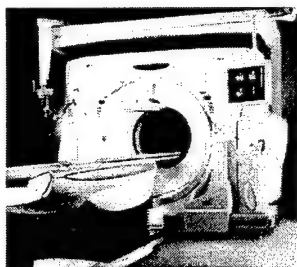


Figure 2a. Pinpoint™ arm (upper left) and CT/fluoroscopy system



Figure 2b. Pinpoint™ arm locked in place to serve as a needle guide

(Courtesy of Marconi Medical Systems:
www.picker.com/ct/ctro/ctrovenue.html)

Semi-autonomous systems have been developed for use in breast and brain tissue biopsy. The Mammotome®, manufactured by Ethicon Endo Inc (Cincinnati, OH) a Johnson and Johnson Company, and the Advanced Breast Biopsy Instrumentation (ABBI®) system, a product of the United States Surgical Corporation (Norwalk, CT), are two widely available breast biopsy systems. Both systems allow remote, image-guided placement and manipulation of the biopsy tool.

The Mammotome breast biopsy system is composed of a thin probe attached to a motorized unit and an integrated vacuum source [5]. Under local anesthesia, the biopsy probe is introduced through a 1/4" inch incision. The probe is navigated under image guidance to the target selected by the physician. Both CT and ultrasound guidance are compatible with the Mammotome. Once in position, a vacuum system draws tissue into the probe core and harvests small samples. The operator can navigate the probe to more than one target per insertion, allowing wide sampling from only one access point [6].

The ABBI system, allows stereotactically guided, mechanically driven fine needle biopsy and a novel "core needle" breast biopsy [7]. Rather than harvesting microhistological specimens from a variety of locations in the breast, the "core needle" breast biopsy option removes a single, solid specimen, which can vary in size

from 5 mm to 20 mm, depending on physician preference. There is some evidence that one-piece cytologic specimens can aid in the diagnosis of certain breast disorders, an advantage of the ABBI core needle biopsy. Studies comparing the effectiveness of the ABBI core needle biopsy to the Mammotome's microhistological approach are ongoing [8]. Because the ABBI core needle system has the potential to remove large pieces of target tissue under physician guidance, it has potential as a treatment modality in addition to a biopsy tool. This application is still under investigation.

Two representative semi-autonomous neurosurgical biopsy systems include the Minerva, developed by the Laboratory of Microengineering at the Swiss Federal Institute of Technology in Lausanne, Switzerland, and the NeuroMate™, manufactured by Integrated Surgical Systems (Davis, CA).

Minerva is a CT guided, multi-function neurosurgical robot [9]. It operates inside a CT gantry with free longitudinal movement allowing cranial scans at any level. Under the physician's remote control, the Minerva robot can manipulate two stereotactic instruments in addition to the tool for automatic penetration of the skin, skull, and meninges. This allows the Minerva to perform a complete stereotactic procedure without physical intervention by the physician. In addition to biopsy, this system has been used for deposition of living encapsulated cells, electrode implantation, placement of radioactive sources, electrostimulation, and tissue aspiration [10].

The NeuroMate stereotactic surgical system was originally developed at the University of Grenoble, France [11, 12] and is now available from ISS. NeuroMate is an image-directed robotic assistant for frameless stereotactic neurosurgical applications (Figure 3). It can function to orient and position surgical instruments under image guidance. Much like Minerva, it is also capable of carrying out surgical procedures under remote physician control.

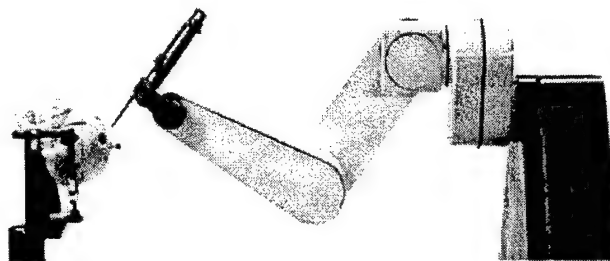


Figure 3. NeuroMate™ robotic assistant for neurosurgical stereotactic applications
(Courtesy of Integrated Surgical Systems: www.robodoc.com/products/neuromate.html)

4. SYSTEM DESCRIPTION AND COMPONENTS

The testbed components (Figure 1) are described in the following sub-sections

4.1 Mobile CT Scanner

The Tomoscan M is a mobile CT scanner (Philips Medical Systems, Eindhoven, Netherlands) that is easily transportable within the hospital. The system has three components including a gantry, CT table, and operator's workstation. The gantry aperture is 60 cm with a maximal field of view of 460 mm. Both the gantry and the CT table can translate, 35 cm and 150 cm respectively. The images have a resolution of 512 by 512 pixels and can be transferred to other systems using the digital imaging and communications in medicine (DICOM) standard. Protocols for cervical, thoracic, and lumbar spine exist with slice thickness options of 2, 3, 5, and 10 mm. The system has a tube voltage of 130 kV and uses a relatively low tube current between 10 and 50 mA, thereby minimizing dose exposure.

4.2 The Robotic System

The robotic system will be based on the PAKY-RCM (Percutaneous Access to the Kidney - Remote Center of Motion) robot that has been initially developed at Johns Hopkins for percutaneous access of the renal collecting system [13, 14]. The robot, schematically represented in Figure 4, consists of a passive positioning and supporting arm (The GREY Arm) [15], an active remote center of motion orientation mechanism (RCM), and a radiolucent needle driver (PAKY). The device will be mounted over the CT table using a bridge fixture as depicted in Figure 4.

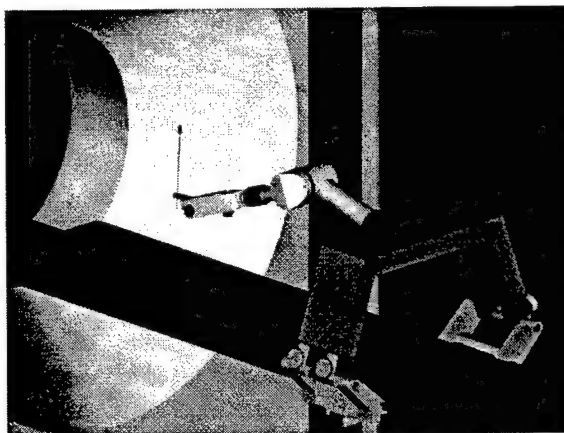


Figure 4. PAKY-RCM robot and bridge fixture

The overall system comprises eleven degrees of freedom (DOF). The first eight DOF are used for the initial positioning of the robot in close proximity of the skin insertion site and firmly locked during the operation. The remaining three DOF, implemented by the RCM robot and PAKY needle driver, are sufficient for orienting and inserting the needle at the desired target through the preset skin insertion point. The main advantage of this minimal kinematic architecture is the inherent safety given by the restricted mobility of the mechanical components. Moreover, separating the kinematics of the orientation and needle insertion yields decoupled needle motion capabilities, thus improving safety.

The needle driver is constructed of acrylic plastic which is radiolucent and easy to manufacture as a sterile disposable part. Driver radiolucency is essential in image-guided procedures for providing unimpeded target visualization. Whereas the driver is sterilized, in clinical use the additional components of the system in close proximity of the operation site are covered with a sterile bag.

The robot accommodates joystick control for simple maneuvers and full computer control for the actual image-guided procedure. The electronic circuitry will be fully enclosed in the supporting bridge of the arm, so that the robot is self-contained and only requires a DC power supply.

The complete system is presently under development. The new design incorporates a major improvement over the first generations of the RCM robot, the "Ball-Worm Transmission" recently developed at the Hopkins URobotics Lab. This transmission fulfills the need for implementing a simple and small no-backlash (no play between the input and output shafts) rotational transmission for miniature surgical robotics. With this addition the RCM exhibits superior motion tracking and positioning capabilities.

4.3 Localizer

The optical localizing system (Hybrid Polaris, Northern Digital, Waterloo, Canada) is used to determine the orientation and position of tracked objects relative to the camera system. Objects are tracked by rigidly attaching retro-reflective spheres or active infrared LED's (IREDs). The spheres or IREDs can be detected by the camera system and used to determine the location and orientation of the object. This version of the Polaris can track up to 3 active and 3 passive tools simultaneously and is controlled via the serial port of the host computer.

By applying reflective spheres directly to the table, we are able to track the CT table and gantry. Similarly, tracking spheres located on the robot and end-effector will enable us to directly monitor the robot position. This is especially important as a safety feature in order to verify the robot's own encoders. Finally, a dynamic reference base (DRB) tracker applied to the patient will enable us to dynamically reference the patient compensating for patient movement or providing a warning when motion occurs. The optimum use for the localizer is still under discussion, but additional uses include robot calibration upon start-up, and assistance in marking the biopsy entry point.

4.4 Biopsy Scenario

The scenario envisioned for robotic spine biopsy is as follows:

1. The patient is positioned on the table and a series of axial scans are obtained
2. The scans are transferred from the operator's workstation to the CT workstation over an Ethernet connection using the DICOM protocol
3. The user interface software allows the physician to select the axial scan of interest and the region to be biopsied (entry location and target point)
4. The entry location for the biopsy is marked on the patient's skin (using the laser lights on the scanner and measuring off the centerline as necessary)
5. The robot is manually positioned at the skin entry point
6. The robot automatically orients the needle and inserts it
7. A CT scan is obtained to verify the needle position
8. The biopsy sample is taken

The testbed will be verified on phantoms and cadavers before any clinical trials are planned. The initial goal is to evaluate the accuracy obtainable using robotically assisted biopsy as compared to the current manual technique as described in Section 2. The interventional phantom shown in Figure 5 will be used in these initial studies.

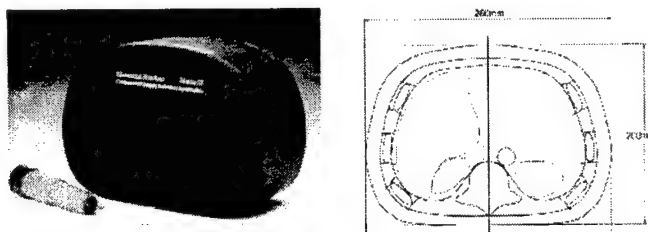


Figure 5. Interventional phantom
(Courtesy of CIRS, Inc. www.cirsinc.com)

5. SYSTEM SOFTWARE DESIGN

Current software systems deployed in surgical environments do not lend themselves to open software architectures that utilize off-the-shelf (OTS) components. These systems are developed from a single

functional perspective; even if multiple functional capabilities are integrated, they are tightly integrated in a closed fashion that results in large, costly, monolithic systems. It then becomes difficult to integrate these systems with systems dedicated to other functional areas. An example of this is the need to offload images from the CT workstation to the NT workstation in our testbed environment (see Figure 1). A more desirable approach is to view technology integration via open software architectures, where various hardware and software components may be integrated on top of a common software “bus”.

Our approach to integrating the hardware and software components of the robotic biopsy testbed is to develop functional component wrappers for each component and integrate them on top of an open architecture. The “wrappers” will shield implementation details from other components, reducing “hardcoded” dependencies between components and enabling the dynamic composition of functionality to meet application requirements. At the same time, the architecture must support drill-down optimizations, fault tolerance, and error handling, to ensure the complex requirements of the application domain are met. To provide a clearer picture of how these components may interact to support the robotic biopsy application, we describe component collaborations using the Unified Modeling Language (UML) collaboration diagram shown in Figure 6.

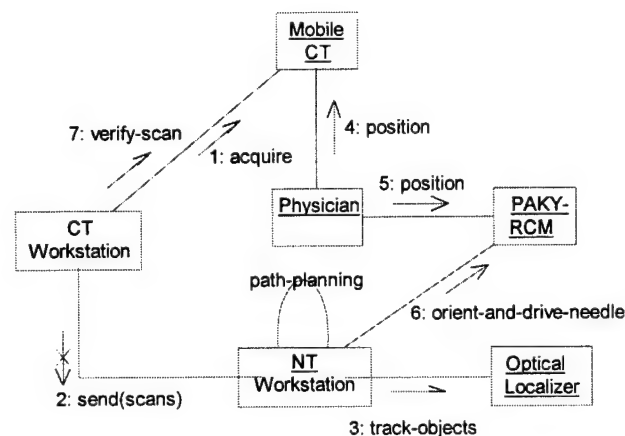


Figure 6. Testbed component collaboration diagram

This figure shows the collaboration between high-level software components, hardware components, and the physician. Although UML collaboration diagrams are typically reserved for software components, we find this a useful notation for expressing workflows between hardware and software components, as well as indicating the role of operator intervention. Steps are numbered according to the sequence in which they are performed. This diagram shows that the CT workstation first acquires a study of images from the Mobile CT. The scans are then sent to the NT workstation, and path planning is done to determine the slice and planned path to the lesion. The NT workstation tells the Optical Localizer to track objects in the application space, which is done continuously for the rest of the procedure. The Mobile CT and PAKY-RCM robot are then positioned manually by the physician. The NT workstation then orients the needle by transmitting path and coordinate information to the robot, and the needle is driven to the target. A verification scan is then taken.

The figure shows at a high level the interactions that must take place between components. Each interaction will in fact be realized at a lower level as a number of messages sent between objects in the environment. In

order to facilitate the interactions between components, the architecture must provide some common services to tie the components together. Such services include DICOM communication (CT and NT workstations), task synchronization, asynchronous and synchronous communication, error handling and event notification, logging, coordinate transformations, and redundant verification (between the localizer, mobile CT, and robotic device). An important, domain-specific example is the mapping of coordinate systems between the optical tracker, NT user interface software, and the robot. This integration task requires a precise mapping of the relative coordinate systems of each component in order to carry out visualization and verification tasks in the application space.

The current architecture is being developed in C++ using DICOM as the image transfer protocol and communication with hardware components via wrapper libraries that talk with specific interfaces (such as serial ports or special-purpose device cards). All component wrappers are being developed with well-defined object interfaces. We view this as a first step towards a more general, open software architecture where hardware and software components are integrated and configured dynamically to meet the requirements of families of surgical applications [16]. We are currently evaluating state-of-the-art middleware technologies such as CORBA, DCOM, and Jini for this purpose.

6. CONCLUSIONS

This paper described an ongoing project in developing a robotic biopsy testbed. Once the system is integrated, it will be used to compare robotically assisted biopsy to the current manual technique. This will require the continued close cooperation between the engineers and physicians and the development of appropriate measures to judge the success of the procedure.

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